IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., and INCEPT LLC,	)	
Plaintiffs,	)	C.A. No. 15-819 (LPS) (CJB)
v.	)	**PUBLIC VERSION**
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE CHRISTOPHER J. BURKE REGARDING HYPERBRANCH MEDICAL TECHNOLOGY, INC.'S MOTION TO STRIKE PLAINTIFFS' IMPROPER INTERROGATORY RESPONSE SHIFTING ASSERTED PRIORITY DATES

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Dear Judge Burke:

HyperBranch respectfully requests that the Court strike Plaintiffs' improper and belated supplemental response to Interrogatory No. 1, which seeks to shift Plaintiffs' asserted priority date for claim 10 of the '034 patent to an earlier date.

This is a very simple dispute. During fact discovery, the Court compelled Plaintiffs to provide an interrogatory response specifically identifying dates of conception and reduction to practice. They did so and relied on those dates for well over a year—including throughout the end of fact discovery, expert discovery, and dispositive motions. Now, less than two months before trial begins, Plaintiffs seek to change those dates. Changing the priority date at the eleventh hour is highly prejudicial to HyperBranch, and Rule 37 forbids it.

The Court ordered Plaintiffs to provide priority dates fourteen months ago. At the very outset of discovery, HyperBranch propounded interrogatories seeking Plaintiffs' asserted priority date for each of its asserted claims. (Ex. 1, Defendant's First Set of Interrogatories.) Plaintiffs refused to provide a meaningful response—failing to provide any dates of conception and reduction to practice. HyperBranch moved to compel an identification of Plaintiffs' asserted priority dates. Rejecting Plaintiffs' argument that the priority date was not "at issue," the Court ordered Plaintiffs to "provide supplemental responses to HyperBranch's interrogatories Number 1 and 2, and in doing so, to specify in those responses the individuals who contributed to the conception **and the asserted priority date** for the claims on a claim-by-claim basis." (D.I. 380-1 at 17:6-11.)

In response to the Court's order, Plaintiffs identified November 9, 2001, as the priority date for claim 10 of the '034 patent. (Ex. 2, Plaintiffs' Supplemental Response to Defendant's Interrogatories Nos. 1 & 2.) This supplementation occurred in December of 2016. Following this initial supplement, Plaintiffs did not again amend or supplement their response during discovery to identify a different date. Thus, for the final six months of fact discovery, the whole of expert discovery, and the entirety of dispositive motions practice, the parties operated under Plaintiffs' assertion that claim 10 of the '034 patent was entitled to a priority date of November 9, 2001.

Plaintiffs' Supplemental Interrogatory Response attempts to change the asserted priority date. As the Court is aware, "Plaintiffs admittedly did not develop [their biocompatibility theory] until September 2017." (Ex. 3, 2017-12-28 Oral Order.) Plaintiffs' late-disclosed theory altered the schedule and has required the parties and the Court to expend substantial additional resources on supplemental expert reports, claim construction, and dispositive motions practice. (*See id.*; *see also* D.I. 467; D.I. 500; Ex. 4, 2018-02-05 Oral Order.) Less than two weeks ago, in their final expert report on this theory, Plaintiffs submitted conclusory declarations from certain inventors asserting, for the first time in this two-and-a-half-year-old litigation, that claim 10 of the '034 patent is entitled to a priority date of "at least February 2001." (Ex. 5, 2018-02-18 Surreply Supplemental Expert Report and Declaration of Jimmy Mays.) Plaintiffs also prepared and served supplemental interrogatory responses, which incorporated the surreply expert report and new inventor declarations, and thereby sought to change Plaintiffs' asserted priority date. (Ex. 6, Plaintiffs' Second Supplemental Response to Defendant's Interrogatory No. 1.)

As an indeterminate priority date of "at least February 2001" clearly contradicts Plaintiffs' prior, specific assertion of November 9, 2001, counsel for HyperBranch requested a meet-and-confer to discuss Plaintiffs' improper attempted supplementation. On the meet and confer, Plaintiffs' counsel confirmed that the change in priority date was not based on any

change of facts or newly discovered information, but was instead based on Plaintiffs' "appreciating" the import of HyperBranch's invalidity theories.[1]

Plaintiffs' change in priority date violates Rule 37 and should be stricken. Rule 37 is straightforward: "If a party fails to provide information . . . the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). Courts in the Third Circuit follow the *Pennypack* test, which lays out five factors for determining whether the sanction of preclusion under Rule 37 is warranted. *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977). These factors weigh heavily in HyperBranch's favor.

***Pennypack* Factor 1: HyperBranch has been prejudiced.** Under Court order, Plaintiffs avowed that claim 10 of the '034 patent was entitled to a priority date of November 9, 2001. Until last week, Plaintiffs never wavered from this position. Accordingly, HyperBranch deposed the inventors, developed invalidity theories, asserted prior art, and relied on the state of the art based on this date. When Plaintiffs disclosed new theories of validity after the close of fact discovery, they still relied on this date and, again, HyperBranch responded accordingly. In essence, HyperBranch's entire invalidity case against claim 10 of the '034 patent has been premised on a priority date of November 9, 2001. If permitted, Plaintiffs' ambush tactics would force HyperBranch, on the eve of trial and months after fact and expert discovery closed, to address an entirely new invention story. This Court has previously struck such untimely assertions of new theories as prejudicial. *See* D.I. 384 (striking undisclosed multi-party market theory of lost profits); *see also HSM Portfolio LLC v. Elpida Memory Inc.*, No. 11-770-RGA, 2016 WL 552543, *2 (D. Del. Feb. 11, 2016) (striking new infringement theories and noting "that is precisely the problem however, as Plaintiffs should not be permitted to advance new theories in a reply report"); *Walker Digital, LLC v. Google Inc.*, Civ. No. 11-309-SLR, 2013 WL 2949109, at *2 (D. Del. June 14, 2013) (striking the plaintiff's new infringement theories because "[defendant] was not given the opportunity to participate in the discovery process related thereto").

***Pennypack* Factors 2 and 3: Prejudice to HyperBranch cannot be cured without substantially disrupting trial.** Without a wholesale reevaluation of Plaintiffs' newly asserted priority dates—including discovery of corroborating or contradictory documentation and additional inventor depositions—HyperBranch will be unable to offer a fully informed invalidity case at trial. To cure this prejudice, the Court would, at a minimum, need to reopen fact discovery, stay all deadlines, allow HyperBranch to assert additional invalidity theories

[1] Plaintiffs will undoubtedly attempt to paint their supplementation as a response to HyperBranch's identification of the Jacobs prior art reference that could not have been made during fact discovery. This argument is a red herring. First, to the extent Plaintiffs seek to argue that their priority date is dependent on HyperBranch's invalidity theories, the Court has already rejected this argument. (*See* D.I. 380-1 at 17:12-16 (THE COURT: "I disagree with plaintiffs' position that those responses aren't relevant until the defendant has, quote, 'put at issue a relevant piece of prior art by citing to some reference that is alleged to,' quote, 'put the reference at issue.'").) Second, Jacobs was indisputably in Plaintiffs' possession during fact discovery—indeed it is cited on the face of the '034 patent. Third, HyperBranch identified numerous publications to support its invalidity and state of the art arguments in this case which are prior art under a November 2001 date, but would be antedated by a February 2001 date. (*See, e.g.*, D.I. 403, Ex. 161 ("Wallace JMBR" – May 2001); D.I. 403, Ex. 134 ("Trollsas '889" – June 15, 2001).) As such, Plaintiffs already had motivation to ascertain the earliest correct priority date well before HyperBranch's identification of Jacobs.

and/or prior art references, and submit a supplemental expert report on invalidity. Such an exercise would undoubtedly push back the looming April 16, 2018 trial date.

***Pennypack* Factor 4: Plaintiffs' shifting litigation tactics evince willful disregard of discovery rules**. This is not the first time that Plaintiffs have flouted their discovery obligations under the Federal Rules. Much like their assertion of a multi-player market in contravention to their interrogatory responses (*see* D.I. 384), Plaintiffs seek to completely ignore the priority dates asserted during fact discovery and adopt a contradictory position at this late hour. Plaintiffs attempt to justify their change of priority date as a proper supplementation under Rule 26(e). This justification completely ignores Plaintiffs' obligations to conduct an actual and thorough investigation of the facts underlying their asserted November 9, 2001 date. Everything contained in the supplemental declarations was known and available to the inventors as of December 2016—when the Court compelled Plaintiffs to assert priority dates. Either Plaintiffs' investigation turned up these facts and Plaintiffs did not disclose them, or Plaintiffs did not conduct a reasonable investigation despite the Court's order. In either case, Plaintiffs should not be allowed to change their assertions 14 months after the fact.

***Pennypack* Factor 5: Plaintiffs may still challenge HyperBranch's invalidity defense.** Striking Plaintiffs' belated supplementation does not preclude Plaintiffs from challenging HyperBranch's invalidity case at trial. Plaintiffs may still argue that HyperBranch's prior art references do not qualify as prior art, do not disclose required elements, or are otherwise not invalidating. Granting HyperBranch's motion simply holds Plaintiffs to the positions they took during discovery—positions which formed the basis for HyperBranch's invalidity defense.

Allowing Plaintiffs to benefit from a material change in their validity positions on the eve of trial is exactly the situation the Federal Rules seek to prevent. Striking Plaintiffs' attempted change-of-heart is the appropriate remedy. *See e.g.*, *Steele v. Aramark Corp.*, 535 F. App'x 137, 143 (3d Cir. 2013) (affirming the District Court's decision striking an affidavit containing a "new and materially different allegation"); *Parallel Networks Licensing, LLC v. Microsoft Corp.*, No. 13-2073(KAJ), slip op. at 9 (D. Del. Apr. 10, 2017) (Jordan, J. by designation) (striking infringement theory first introduced weeks before trial); *Elbit Sys. Land & C4I Ltd. v. Hughes Network Sys., LLC*, No. 2:15-cv-00037, 2017 WL 2651618, at *9-*10 (E.D. Tex. June 20, 2017) (striking supplemental interrogatory responses seeking to change priority date").

For these reasons, HyperBranch respectfully requests that the Court (i) strike Plaintiffs' second supplemental response to Interrogatory No. 1; (ii) strike paragraphs 5-7 from the Surreply Supplemental Report and Declaration of Dr. Jimmy Mays; (iii) strike the corresponding supplemental declarations of Pathak, Sawhney, and Edelman; and (iv) preclude Plaintiffs from offering at trial testimony, evidence, and/or argument regarding the changed priority date at trial.

Respectfully,

/s/ Thomas C. Grimm

Thomas C. Grimm (#1098)

TCG/dla
Enclosures
cc: Clerk of the Court (by hand delivery, w/encls.)
Counsel of Record (by e-mail, w/encls.)

EXHIBIT 1

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., and INCEPT LLC,	)	
Plaintiffs,	)	C.A. No. 15-819 (LPS) (CJB)
v.	)	
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	)	
Defendant.	)	

DEFENDANT'S FIRST SET OF INTERROGATORIES TO PLAINTIFFS

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure and the Local Rules, Defendant HyperBranch Medical Technology, Inc. ("HyperBranch") requests that Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC (collectively, "Integra" or "Plaintiffs") answer each of the interrogatories set forth below. Plaintiffs are required to supplement their responses to this discovery pursuant to the Federal Rules of Civil Procedure.

DEFINITIONS

HyperBranch hereby incorporates by reference the Definitions set forth in its First Set of Requests for the Production of Documents and Things to Plaintiff. Additionally, as used herein, unless specifically indicated otherwise, the following terms shall have the indicated meanings:

A. The term "Identify" means:

i. As applied to an individual, to state the person's full name, the person's last known residence and business address, the person's last known residence and business telephone number; and the person's business, occupation, or profession.

ii. As applied to a Person other than a natural person, to state the entity's full name, place and date of incorporation or formation, principal place of business or activity, and to Identify the natural persons within that entity having knowledge of the matter with respect to which that entity is named.

iii. As applied to a Document (whether or not any claim of privilege is made in respect thereof), to provide a description of the Document (i.e., letter, memorandum, handwritten notes, etc.) and a summary of its contents; the date the Document was prepared: the identity of the person(s) who prepared and/or signed the Document; the identity of the Person(s) who received the Document or copies thereof; whether a copy of the Document is in your possession or control, and if not, the identity of the Person(s) who have possession or control of the Document; and the identity of any enclosures, attachments, or other Document accompanying the Document.

INSTRUCTIONS

The following instructions shall apply to each of the Interrogatories herein:

1. In answering the following Interrogatories, furnish all available information, including information in the possession, custody, or control of any of Plaintiffs' attorneys, directors, officers, agents, employees, representatives, associates, investigators or division affiliates, partnerships, parents or subsidiaries, and Persons under Plaintiffs' control, who have the best knowledge. If you cannot fully respond to the following Interrogatories after exercising due diligence to secure the information requested thereby, so state, and specify the portion of each Interrogatories that cannot be responded to fully and completely. In the latter event, state what efforts were made to obtain the requested information and the facts relied upon that support the contention that the Interrogatories cannot be answered fully and completely; and state what

knowledge, information or belief Plaintiffs have concerning the unanswered portion of any such Interrogatories.

2. If any information requested is claimed to be privileged or otherwise, please provide all information falling within the scope of the Interrogatory which is not privileged.

3. If Plaintiffs' response to a particular Interrogatory is a statement that Plaintiffs lack the ability to comply with that Interrogatory, Plaintiffs must specify whether the inability to comply is because the particular item or category of information never existed, has been destroyed, has been lost, misplaced, or stolen, or has never been, or is no longer, in Plaintiffs' possession, custody, or control, in which case the name and address of any Person or entity known or believed by you to have possession, custody, or control of that information or category of information must be identified.

4. Plaintiffs' obligation to respond to these Interrogatories is continuing and its responses are to be supplemented to include subsequently acquired information in accordance with the requirements of Rule 26(e) of the Federal Rules of Civil Procedure.

INTERROGATORIES

INTERROGATORY NO. 1.

Describe with particularity the circumstances surrounding the invention and patenting of the inventions claimed in the Asserted Patents, including the precise date of conception, the Persons involved and the nature of their involvement, the dates of actual and constructive reduction to practice, the steps constituting diligence from conception to actual or constructive reduction to practice, drafting and submission of invention disclosures or laboratory notebooks, patent application drafting, all factual and legal bases for any contention that any asserted claims are entitled to an invention or priority date that is earlier than the date of priority claimed on the face of the patent, identification of all persons involved in the conception and/or reduction to practice, along with a description of his or her involvement and all Documents that You contend corroborate any of the foregoing.

INTERROGATORY NO. 2.

Identify each product or process ever made, used, sold, offered for sale, or imported by You, by the named inventors of the Asserted Patents, by any licensee, owner, or assignee, of the Asserted Patents, by any Third Party, or Defendant that You believe or have believed embodies, practices, or uses any of the alleged inventions claimed in the Asserted Patents, including by specifying the product or process name, the first dates each product or process was made, sold, or licensed, the date on which you first became aware of such product or process, the claim(s) of the Asserted Patents that were embodied, practiced, and/or used in or by each such product or process, the revenue derived from sale of the product or service, and a chart describing where in each product or process each limitation of such claim is found on an claim element-by-claim element basis, including an identification of all Evidence supporting such contention.

INTERROGATORY NO. 3.

Describe in detail the first sale, first offer for sale, first public use, first public disclosure or first public display of any apparatus and/or method embodying the purported invention of the Asserted Patents and identify the date of such offer to sell, sale, public use, public disclosure or public display, the identification of the product or process that was the subject of the offer to sell, sale, public use, public disclosure or public display and the identification of the Person to whom such activity was directed and all Persons with knowledge thereof and all Documents relating thereto.

INTERROGATORY NO. 4.

Separately, for each asserted claim of the Asserted Patents, state whether You contend that there are secondary considerations that should be considered by the Court in connection with its 35 U.S.C. § 103 determination of the validity of the Asserted Patents, including but not limited to commercial success, long-felt but unmet need, unexpected results, copying by others, praise from others in the field, and, if the response is anything other than an unqualified negative, describe in detail all facts relating to each secondary consideration that You intend to rely upon and why and/or how such consideration demonstrates nonobviousness, identify all Persons with knowledge thereof and all Documents relating thereto.

INTERROGATORY NO. 5.

Describe in detail all agreement(s), potential agreement(s) or License(s) with any Person or Entity relating to the Asserted Patents or Related Patents and Applications. A complete response will include, but is not limited to: a detailed description of each identifiction of a party allegedly using the inventions of the Asserted Patents, negotiation, offer, request, and counteroffer relating to any agreement, potential agreement, or License; all analysis performed

by and/or exchanged with You or any Persons or Entities during any negotiation for an agreement, potential agreement or License; the date(s) on which each agreement or License became effective; the Persons responsible for negotiating each agreement, potential agreement or License; the consideration paid for each agreement, potential agreement, or License; and an identification of all Documents related to each agreement, potential agreement or License.

INTERROGATORY NO. 6.

State whether Plaintiffs have ever conducted, or caused to be conducted, an investigation of the alleged infringement, scope, validity, patentability, or enforceability of the subject matter disclosed and/or claimed in the Asserted Patents, including the date(s) of such investigation, the scope of such investigation (including but not limited to the identification of all Prior Art and products or services considered), the identity and role of all Persons involved in any way in the investigation, each and every conclusion of the investigation and a summary of the analysis, and identify all Documents (by Bates number) concerning any such investigation.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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October 23, 2015

CERTIFICATE OF SERVICE

I hereby certify that on October 23, 2015, copies of the foregoing were caused to be served upon the following in the manner indicated:

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EXHIBIT 2

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., AND INCEPT LLC, Plaintiffs, v. HYPERBRANCH MEDICAL TECHNOLOGY, INC., Defendant.	C.A. No. 15-819-LPS-CJB

PLAINTIFFS' SUPPLEMENTAL OBJECTIONS AND ANSWERS TO HYPERBRANCH'S INTERROGATORIES NOS. 1 AND 2

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, the Local Rules for the U.S. District Court for the District of Delaware, and subject to their rights to supplement these objections later in discovery, Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC (collectively "Plaintiffs," as well as "Integra," "Integra Sales," "Confluent," and "Incept," respectively) hereby provide the following supplemental objections and responses to Defendant HyperBranch Medical Technology's ("HyperBranch") First Set of Interrogatories (Nos. 1 and 2) , including each and every definition, instruction, and interrogatory contained therein (collectively "HyperBranch's First Set of Interrogatories"). The fact that Plaintiffs provide an answer to an interrogatory does not constitute an admission or acknowledgement that the interrogatory is proper, that the answers sought are within the bounds of discovery, or that requests for similar information will be treated in a similar fashion. Plaintiffs do not waive any objection by producing such documents, things, or answers, and Plaintiffs reserve the right to continue investigating these matters, to supplement their objections, and to object to future discovery on the same or related matters. Plaintiffs

further reserve the right to object to the admissibility of any answer produced pursuant to these interrogatories, in whole or in part, on any ground including without limitation materiality, relevance, and privilege.

GENERAL OBJECTIONS

Plaintiffs incorporate by reference their General Objections and Objections to Specific Definitions to HyperBranch's Requests for Production. Each of these General Objections is incorporated into the specific objections set forth below, whether or not separately set forth therein.

1. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks to impose upon Plaintiffs any obligation or responsibility broader than, different from, or in addition to those obligations and requirements mandated by the Federal Rules of Civil Procedure, the Federal Rules of Evidence (collectively, the "Federal Rules"), and the Local Rules for the United States District Court for the District of Delaware (the "Local Rules").

2. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks the disclosure of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law. Plaintiffs do not intend to produce such privileged or protected documents or information. To the extent that any document or information which is properly subject to any such privilege or protection is inadvertently produced in connection with an answer to an interrogatory, such inadvertent disclosure is not to be construed as a waiver of such privilege or protection, and such document and information, and all copies thereof, shall be returned to counsel for Plaintiffs, in accordance with Fed. R. Evid. 502(b), Fed. R. Civ. P. 26(b)(5)(B), and any relevant Order entered by the Court. Further,

Plaintiffs will limit their privilege log to pre-lawsuit privileged or protected documents or information, if any exist.

3. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent they contain misstatements of fact and/or inaccurate assumptions. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it is overly broad, unduly burdensome, or oppressive. Plaintiffs further object to each and every definition, instruction, and interrogatory to the extent it calls for information that is irrelevant to any claim or defense in this action.

4. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks information already in the possession, custody, or control of HyperBranch as being overly broad, unduly burdensome, expensive, and inconsistent with the Federal Rules.

5. Plaintiffs object to each and every definition, instruction, and interrogatory as being unduly burdensome to the extent it seeks facts, documents, and/or information that is publicly available, unreasonably cumulative or duplicative, or already known and equally available to HyperBranch.

6. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it is vague, ambiguous, fails to describe the information sought with the required reasonable particularity, or is so unintelligible that Plaintiffs cannot ascertain what information is responsive.

7. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks to impose upon Plaintiffs an obligation to investigate or discover information, materials, or documents from any entity other than Plaintiffs, including, but not limited to, third parties or non-parties.

8. Plaintiffs' agreement to furnish information in response to HyperBranch's Interrogatories shall not be deemed to constitute an admission as to its relevancy, nor is it intended to waive any right to object to its admissibility at trial.

9. Plaintiffs object to each interrogatory that requests "each," "every," or "all" (and to similar overly broad terms) information or documents as overbroad and unduly burdensome. Plaintiffs will undertake a diligent and reasonable investigation to gather information in their possession, custody, or control that is responsive to the non-objectionable portions of each interrogatory.

10. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it contains subparts, is compound and conjunctive, and is otherwise inconsistent with or exceeds the number of interrogatories permitted by any relevant Order entered by the Court. The Court has set a limit of 25 interrogatories for each side. In answering any or all of these Interrogatories or subparts, Plaintiffs do so without waiver of their right to object to and refuse to answer any future Interrogatories on the grounds that such Interrogatories are in excess of the number permitted by the Federal and Local Rules and the Court's Scheduling Order.

11. In addition to these General Objections, Plaintiffs have specific objections as set forth below. By stating these specific objections, Plaintiffs do not waive any of the General Objections that may also be applicable to specific interrogatories.

OBJECTIONS TO SPECIFIC DEFINITIONS

1. Plaintiffs object to the definition of the terms "Plaintiffs," "You," and "Yours" to the extent those terms are overly broad and purport to require Plaintiffs to provide information and/or documents that are not currently within their possession, custody, or control. Plaintiffs object to the definitions of the terms "Plaintiffs," "You," and "Yours" as seeking the disclosure

of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law, in that the definitions specifically cover "attorneys."

2. Plaintiffs object to the definition of "Accused Products" as overbroad, unduly burdensome, and irrelevant to any issue in this matter as "any and all products, activities, services, processes, systems, apparatuses, or things that Plaintiffs accuse of infringing the Asserted Patents in this Action, including Adherus Autospray Dural Sealant, Adherus Dural Sealant, and Adherus Spinal Sealant" include information, products, and/or documents that are not currently within the possession, custody, or control of Plaintiffs. Indeed, this definition explicitly includes documents and things which are in the exclusive control of Defendant and Third Parties.

3. Plaintiffs object to the definition of the term "each" to the extent that the definition purports to impose a meaning broader than the definition provided in the Federal Rules.

4. Plaintiffs object to the definition of "Prior Art" as overbroad, unduly burdensome, and irrelevant to any issue in this matter as "all things, patents, publications, disclosures, sales, or other acts or occurrences included within the broadest meaning of 35 U.S.C. § 102 (or any subpart thereof) and 35 U.S.C. § 103" and "publications, patents, patent applications, inventions by others, uses, sales or offers for sale, and disclosures" purports to require Plaintiffs to provide information and/or documents that are not currently within their possession, custody, or control.

OBJECTIONS AND ANSWERS TO SPECIFIC INTERROGATORIES

INTERROGATORY NO. 1 [9]. On a claim-by-claim basis for each and every claim of the Asserted Patents, identify each individual who You contend contributed to the conception of the invention set forth in each claim, including all supporting facts and evidence of the contribution to the conception of each claim by the identified individual(s) and the dates of such contribution(s).

OBJECTION AND ANSWER TO INTERROGATORY NO. 1 [9]:

Plaintiffs incorporate their General Objections and Objections to Specific Definitions by reference. Plaintiffs object to this interrogatory to the extent it purports to be a single interrogatory as it contains multiple and distinct subparts. Plaintiffs further object to this interrogatory to the extent it purports to be HyperBranch's first interrogatory. HyperBranch previously served Interrogatory Nos. 1-6 on October 23, 2015, and Interrogatory Nos. 7-8 on December 9, 2015. Thus, this interrogatory is HyperBranch's ninth interrogatory. Plaintiffs further object to this interrogatory as being unreasonably cumulative or duplicative, or already known to HyperBranch. *See* Interrogatory No. 1 served by HyperBranch on October 23, 2015. Plaintiffs further object to this interrogatory to the extent it seeks the disclosure of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law. Plaintiffs further object to the interrogatory as overbroad and unduly burdensome in that it requests identification of "all supporting facts and evidence of the contribution to the conception of each claim." Plaintiffs further object to this interrogatory as premature and irrelevant to the extent it is a contention interrogatory that seeks to impose a burden on Plaintiffs to provide a rebuttal position on conception of the inventions claimed in the patents-in-suit prior to the provision of any contention of invalidity of the claims that Defendant is required to provide on November 4, 2016. Validity, including validity of conception and proper inventorship is presumed by the issuance of the patent. Defendant bears the burden of establishing through its

invalidity contentions that there is an issue as to validity that would require Plaintiffs to prove an earlier date of invention or confirm the contribution of a listed inventor to the claims of the patents-in-suit. To date, Defendants validity contentions have not met that burden. Plaintiffs also object to this interrogatory to the extent it calls for legal argument and/or expert testimony, which Plaintiffs may provide, in due course and in accordance with the Court's Scheduling Order.

Subject to and without waiving its objections, Plaintiffs incorporate by reference their response to Interrogatory No. 1 served on November 13, 2015 and all supplements thereto and the Rebuttal Expert Report of Dr. Jimmy Mays and further respond that based on present information Chandrashekhar P. Pathak, Amarpreet S. Sawhney, and Peter G. Edelman contributed to the conception of one or more claims of the '034 Patent, the '406 Patent, the '5,705 Patent, the '566 Patent and the '418 Patent. Plaintiffs further respond that based on present information Amarpreet S. Sawhney, Steven Bennett, and Peter G. Edelman contributed to the conception of one or more claims of the '3,705 Patent. Defendants' present invalidity contentions do not place in dispute the conception or the named inventor's individual contributions to conception of any of the claims. Accordingly, Plaintiffs presently intend to rely on the effective filing date for each of patents-in-suit (including those patents and patent applications to which priority is claimed), including any evidence presented during prosecution of the patents-in-suit (including those patents and patent applications to which priority is claimed), the recitation of the named inventors on the face of each of the patents-in-suit, and the prior sworn deposition testimony (including exhibits used in those depositions) in this matter of the named inventors to identify the dates and individuals contributing to the conception of each of the claims of the patents-in-suit and the prior sworn testimony and multiple expert reports,

rebuttal expert reports, and/or declarations of Dr. Jimmy Mays that have previously been provided in this matter. Plaintiffs further respond that they have produced non-privileged documents pursuant to Federal Rule of Civil Procedure 33(d) (including the patents-in-suit, the patents and applications from which the patents-in-suit claim priority, the prosecution histories of these patents and patent applications, and the laboratory notebooks and the reports summarizing the laboratory work and notebooks of the inventors and individuals working under their direction (*See, e.g.,* Experimental Reports or Technical Documents having an ER[###] or TD-[###] identification)) from which HyperBranch may derive or ascertain information responsive to this interrogatory. Investigation of the facts is ongoing and Plaintiffs reserve the right to supplement this response to identify additional information and/or documents as more facts arise in discovery or as Defendant's invalidity contentions are fully and completely provided, in accordance with the Rules.

SUPPLEMENTAL OBJECTION AND ANSWER TO INTERROGATORY NO. 1[9]:

Subject to and without waiving any of its objections, based on information currently available to Plaintiffs and further to the Court's Order during the telephone conference on December 1, 2016, Plaintiffs supplement their previous response by stating that to the extent that Plaintiffs understand this interrogatory, Plaintiffs identify the following individuals who Plaintiffs currently contend to have contributed to the conception of the inventions set forth in the Asserted Claims and Plaintiffs contentions as to the date of conception of the inventions set forth in the Asserted Claims (to the extent that the "Earlier Conception Date" column is blank for any respective row, in the following tables, Plaintiffs are currently relying on the "Earlier Effective Filing Date" as also the "Earlier Conception Date"):

U.S. Patent 7,009,034

Claim	Earlier Effective Filing Dates	Earlier Conception Date*	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
3	December 4, 1998 and December 3, 1999		Pathak
4	December 4, 1998 and December 3, 1999		Pathak
5	December 4, 1998 and December 3, 1999		Pathak
6	November 9, 2001	February 2001	Pathak, Sawhney, Edelman
9	December 4, 1998 and December 3, 1999		Pathak
10	November 9, 2001		Pathak, Sawhney, Edelman
11	December 4, 1998 and December 3, 1999		Pathak
12	December 4, 1998 and December 3, 1999		Pathak
13	December 4, 1998 and December 3, 1999		Pathak
14	December 3, 1999		Pathak
15	December 4, 1998 and December 3, 1999		Pathak
16	December 4, 1998 and December 3, 1999		Pathak
17	December 3, 1999		Pathak
18	December 4, 1998 and December 3, 1999		Pathak
19	December 4, 1998 and December 3, 1999		Pathak
20	December 4, 1998 and December 3, 1999		Pathak
21	December 4, 1998 and December 3, 1999		Pathak

U.S. Patent No. 7,332,566

Claim	Earlier Effective Filing Dates	Earlier Conception Date	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
3	November 9, 2001	February 2001	Pathak, Sawhney, Edelman

4	December 4, 1998 and December 3, 1999		Pathak
6	December 4, 1998 and December 3, 1999		Pathak
7	November 9, 2001		Pathak, Sawhney, Edelman
8	December 4, 1998 and December 3, 1999		Pathak
9	November 9, 2001		Pathak, Sawhney, Edelman
10	December 3, 1999		Pathak
11	December 4, 1998 and December 3, 1999		Pathak
12	December 4, 1998 and December 3, 1999		Pathak
14	December 4, 1998 and December 3, 1999		Pathak
15	November 9, 2001		Pathak, Sawhney, Edelman
16	December 4, 1998 and December 3, 1999		Pathak
18	December 4, 1998 and December 3, 1999		Pathak
19	November 9, 2001		Pathak, Sawhney, Edelman
20	December 4, 1998 and December 3, 1999		Pathak
21	December 4, 1998 and December 3, 1999		Pathak
22	December 4, 1998 and December 3, 1999		Pathak
23	November 9, 2001		Pathak, Sawhney, Edelman
24	December 4, 1998 and December 3, 1999		Pathak
25	December 4, 1998 and December 3, 1999		Pathak
27	November 9, 2001	February 2001	Pathak, Sawhney, Edelman
28	December 4, 1998 and December 3, 1999		Pathak
30	December 4, 1998 and December 3, 1999		Pathak
31	November 9, 2001		Pathak, Sawhney, Edelman
32	December 3, 1999		Pathak

33	December 4, 1998 and December 3, 1999		Pathak
34	November 9, 2001		Pathak, Sawhney, Edelman
35	December 4, 1998 and December 3, 1999		Pathak
36	December 4, 1998 and December 3, 1999		Pathak
37	December 4, 1998 and December 3, 1999		Pathak
38	November 9, 2001		Pathak, Sawhney, Edelman

U.S. Patent No. 7,592,418

Claim	Earlier Effective Filing Dates	Conception Date	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
3	December 4, 1998 and December 3, 1999		Pathak
4	November 9, 2001	February 2001	Pathak, Sawhney, Edelman
5	December 4, 1998 and December 3, 1999		Pathak
6	December 4, 1998 and December 3, 1999		Pathak
7	November 9, 2001		Pathak, Sawhney, Edelman
8	December 3, 1999		Pathak
9	December 4, 1998 and December 3, 1999		Pathak
10	November 9, 2001		Pathak, Sawhney, Edelman
11	December 4, 1998 and December 3, 1999		Pathak
13	December 4, 1998 and December 3, 1999		Pathak
14	December 4, 1998 and December 3, 1999		Pathak
15	December 4, 1998 and December 3, 1999		Pathak
16	December 4, 1998 and December 3, 1999		Pathak
22	December 4, 1998 and December 3, 1999		Pathak

23	December 4, 1998 and December 3, 1999		Pathak
24	December 4, 1998 and December 3, 1999		Pathak
25	December 4, 1998 and December 3, 1999		Pathak
26	November 9, 2001		Pathak, Sawhney, Edelman
27	December 4, 1998 and December 3, 1999		Pathak
28	December 4, 1998 and December 3, 1999		Pathak
29	December 4, 1998 and December 3, 1999		Pathak
30	November 9, 2001		Pathak, Sawhney, Edelman

U.S. Patent No. 6,566,406

Claim	Earlier Effective Filing Dates	Conception Dates	Inventors
1	December 4, 1998		Pathak
2	December 4, 1998		Pathak
6	December 4, 1998		Pathak
7	December 4, 1998		Pathak
8	December 4, 1998		Pathak
10	December 4, 1998		Pathak
12	December 4, 1998		Pathak
14	December 3, 1999		Pathak, Sawhney, Edelman
15	December 3, 1999		Pathak, Sawhney, Edelman
16	December 4, 1998		Pathak
19	December 4, 1998		Pathak
21	December 4, 1998		Pathak
23	December 3, 1999		Pathak, Sawhney, Edelman
24	December 3, 1999		Pathak, Sawhney, Edelman
25	December 3, 1999		Pathak, Sawhney, Edelman

U.S. Patent No. 8,003,705

Claim	Earlier Effective Filing Dates	Conception Dates	Inventors
1	May 28, 2008	December 2000	Sawhney, Bennett, Edelman
4	November 9, 2001		Sawhney, Edelman
5	November 9, 2001		Sawhney, Edelman
6	November 9, 2001		Sawhney, Edelman
11	November 9, 2001		Sawhney, Edelman
12	November 9, 2001		Sawhney, Edelman
13	November 9, 2001		Sawhney, Edelman
16	May 28, 2008	December 2000	Sawhney, Bennett, Edelman
19	May 28, 2008	December 2000	Sawhney, Bennett, Edelman

U.S. Patent No. 8,535,705

Claim	Earlier Effective Filing Dates	Conception Dates	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
5	December 4, 1998 and December 3, 1999		Pathak
6	December 4, 1998 and December 3, 1999		Pathak
7	December 4, 1998 and December 3, 1999		Pathak
9	December 3, 1999		Pathak, Sawhney, Edelman
12	December 4, 1998 and December 3, 1999		Pathak
15	December 4, 1998 and December 3, 1999		Pathak
17	December 4, 1998 and December 3, 1999		Pathak

Plaintiffs reserve the right to amend or supplement this response as this case proceeds.

INTERROGATORY NO. 2 [10]. On a claim-by-claim basis for each and every claim of the Asserted Patents, identify what You contend to be the effective filing date for the claim, including all supporting facts and evidence for the identified effective filing date such as, without limitation, the specific page and lines of any prior filed applications that you contend supports Your identified effective filing date for each claim.

OBJECTION AND ANSWER TO INTERROGATORY NO. 2 [10]:

Plaintiffs incorporate their General Objections and Objections to Specific Definitions by reference. Plaintiffs object to this interrogatory to the extent it purports to be a single interrogatory as it contains multiple and distinct subparts. Plaintiffs further object to this interrogatory to the extent it purports to be HyperBranch's second interrogatory. HyperBranch previously served Interrogatory Nos. 1-6 on October 23, 2015, and Interrogatory Nos. 7-8 on December 9, 2015. Thus, this interrogatory is HyperBranch's tenth interrogatory. Plaintiffs further object to this interrogatory as being unreasonably cumulative or duplicative, or already known to HyperBranch. *See* Plaintiffs' Responses and Supplemental Responses to Interrogatory Nos. 1 and 8 and Rebuttal Expert Report of Dr. Jimmy Mays, hereby incorporated by reference in their entirety. Plaintiffs further object to this interrogatory to the extent it seeks the disclosure of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law. Plaintiffs further object to the interrogatory as overbroad and unduly burdensome and premature at this stage of the litigation in that it requests identification of "all of the factual and legal bases for that contention, and identify all documents and evidence you claim supports that contention." ." Plaintiffs further object to this interrogatory as premature and irrelevant to the extent it is a contention interrogatory that seeks to impose a burden on Plaintiffs to provide a rebuttal position on the effective filing date of each claim prior to the disclosure of any invalidity contention by the Defendant that puts at issue the effective filing date of any claim on which Defendant has the burden of proof and is required to provide its full and complete invalidity contentions. Validity of the claims is presumed by the issuance of the patent. Defendant bears the burden of establishing through its invalidity contentions that there is an issue

as to validity that would require Plaintiffs to prove an earlier effective filing date. To date, Defendants validity contentions have not met that burden. Plaintiffs further object to this Interrogatory to the extent it contains subparts which, together with the other Interrogatories, exceed the limit under the Federal Rules. Plaintiffs also object to this interrogatory to the extent it calls for legal argument and/or expert testimony, which Plaintiffs may provide, in due course and in accordance with the Court's Scheduling Order.

Subject to and without waiving its objections, Plaintiffs rely on the disclosures provided in the patents-in-suit including the related U.S. applications provided on the front of each of the patents in suit to provide an effective filing date for each of the claims. Particularly, the related U.S. applications listed on the face of the patents-in-suit show that the effective filing date for many of the limitations found in the claims of the patents-in-suit may extend back to at least as early as December 4, 1998 and possibly as early as September 23, 1996. For example, many of the limitations claimed in the patents-in-suit can expressly be found in the text of the related U.S. applications. (*See, e.g.*, visualization agent, precursors, biodegradable polymers, biodegradable polymeric crosslinkers, nucleophilic functional groups, electrophilic functional groups, hydrogel film thickness, and many others). Plaintiffs further respond that they have produced non-privileged documents pursuant to Federal Rule of Civil Procedure 33(d) for which the burden of deriving or ascertaining the answer will be substantially the same for HyperBranch as it is for plaintiffs, namely the patents-in-suit, the patents and applications from which the patents-in-suit claim priority, and prosecution histories of these patents and patent applications.

Plaintiffs also identify Exhibits 57 and 58 to the previous deposition of the inventors along with the transcripts of those depositions (i.e., Amar Sawhney and Steven Bennett) as providing

further information related to the effective filing date of the claims of the patents-in-suit. *See, e.g.*, Steve Bennett deposition transcript at pp. 147-48.

Investigation of the facts is ongoing and Plaintiffs reserve the right to supplement this response to identify additional information and/or documents as more facts arise in discovery and as rebuttal if Defendant meets its burden of setting forth a preliminary contention of invalidity that puts at issue the effective filing date of one or more claims of the patents-in-suit in accordance with the rules and the Scheduling Order in this matter.

SUPPLEMENTAL OBJECTION AND ANSWER TO INTERROGATORY NO. 2[10]:

Subject to and without waiving any of its objections, based on information currently available to Plaintiffs, Plaintiffs supplement their previous response by stating that to the extent that Plaintiffs understand this interrogatory, Plaintiffs incorporate by reference their response to Interrogatory No. 1[9] and all supplements thereto as identifying Plaintiffs current contentions as to the effective filing dates earlier than the filing date of the application that directly issued as the U.S. Patent and supporting evidence for the inventions set forth in the Asserted Claims. Plaintiffs reserve the right to amend or supplement this response as this case proceeds.

AS TO OBJECTIONS ONLY:

DATED: December 9, 2016

/s/ Karen L. Pascale

An Attorney for Plaintiffs, Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on December 9, 2016, I caused true and correct copies of the foregoing document to be served upon the following counsel of record by e-mail:

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EXHIBIT 3

[redacted]

From: ded_nefreply@ded.uscourts.gov
Sent: Thursday, December 28, 2017 8:30:42 AM (UTC-05:00) Eastern Time (US & Canada)
To: ded_ecf@ded.uscourts.gov
Subject: Activity in Case 1:15-cv-00819-LPS-CJB Integra LifeSciences Corp. et al v. HyperBranch Medical Technology, Inc Oral Order

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U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was entered on 12/28/2017 at 8:30 AM EST and filed on 12/28/2017

Case Name: Integra LifeSciences Corp. et al v. HyperBranch Medical Technology, Inc
Case Number: 1:15-cv-00819-LPS-CJB
Filer:
Document Number: No document attached

Docket Text:
ORAL ORDER: The Court, having reviewed the parties' recent December 22, 2017 letter regarding how to address Plaintiffs' biocompatibility theory, hereby ORDERS that Defendant's scheduling proposal, set out on page 3 of that letter, shall be be ADOPTED. The Court agrees, for largely the reasons set out in Defendant's submission, that Defendant's proposal is the most reasonable and appropriate way to address the theory, which (1) Plaintiffs admittedly did not develop until September 2017; and (2) does appear to implicate claim construction issues (issues that Defendant's schedule provides a sensible way to address). Ordered by Judge Christopher J. Burke on 12/28/2017. (dlb)

1:15-cv-00819-LPS-CJB Notice has been electronically mailed to:

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1:15-cv-00819-LPS-CJB Filer will deliver document by other means to:

EXHIBIT 4

[redacted]

From: ded_nefreply@ded.uscourts.gov
Sent: Monday, February 5, 2018 9:29:23 AM (UTC-05:00) Eastern Time (US & Canada)
To: ded_ecf@ded.uscourts.gov
Subject: Activity in Case 1:15-cv-00819-LPS-CJB Integra LifeSciences Corp. et al v. HyperBranch Medical Technology, Inc Oral Order

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U.S. District Court

District of Delaware

Notice of Electronic Filing

The following transaction was entered on 2/5/2018 at 9:29 AM EST and filed on 2/5/2018

Case Name: Integra LifeSciences Corp. et al v. HyperBranch Medical Technology, Inc
Case Number: 1:15-cv-00819-LPS-CJB
Filer:
Document Number: No document attached

Docket Text:
ORAL ORDER: The Court, having reviewed the parties' February 1, 2018 letter, (D.I. [500]), and for the reasons set out in the February 2, 2018 discovery dispute hearing, hereby ORDERS that the schedule listed on page 2 of the letter be ADOPTED.Ordered by Judge Christopher J. Burke on 2/5/2018. (mlc)

1:15-cv-00819-LPS-CJB Notice has been electronically mailed to:

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1:15-cv-00819-LPS-CJB Filer will deliver document by other means to:

EXHIBIT 5

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC, Plaintiffs, v. HyperBranch Medical Technology, Inc., Defendant.	Civil Action No. 15-819 (LPS) (CJB)

SURREPLY SUPPLEMENTAL EXPERT REPORT AND DECLARATION OF DR. JIMMY MAYS

1. In this Surreply Supplemental Expert Report, I have been asked to respond to positions in the First Supplemental Report of Dr. Anthony Lowman.

2. In his First Supplemental Expert Report, Dr. Lowman's includes a new argument that claim 10 of the '034 patent is anticipated by "SprayGel™ as New Intraperitoneal Adhesion Prevention Method for Use in Laparoscopy and Laparotomy," VR Jacobs, E Lehmann-Willenbrock, M Kiechle, L Mettler, ISGE 10 Convention, Chicago March 2001 ("Jacobs"). In my opinion, Dr. Lowman has failed to demonstrate that Jacobs is prior art, as explained below.

3. I understand that a reference does not qualify as prior art under 35 U.S.C. § 102(a) if that reference describes the inventors' own work or the work of another at the direction of the inventors or the work of another who obtained the subject matter directly or indirectly from the inventors. I have reviewed the attached Declaration of Dr. Sawhney and related exhibit. Dr. Sawhney's Declaration states at Paragraph 4:

> The authors of Jacobs – Drs. Jacobs, Lehmann-Willenbrock, and Mettler – were a team of doctors commissioned by Confluent to conduct a clinical evaluation of SprayGel in Europe. As President and CEO, I assembled, directed, and supervised

> that team of doctors that performed the clinical evaluation of SprayGel. I developed the protocol for the clinical evaluation of SprayGel performed by Drs. Jacobs, Lehmann-Willenbrock, and Mettler. To the extent that others contributed to the design and analysis of the clinical evaluation, they did so under my direction and supervision. I was the sole source of the SprayGel materials that were used in the clinical evaluation conducted by Drs. Jacobs, Lehmann-Willenbrock, and Mettler. Drs. Jacobs, Lehmann-Willenbrock, and Mettler were working under my direction as clinical evaluators and were not involved in the conception of the subject matter disclosed in Jacobs.

4. In my opinion, these unrefuted facts establish that Jacobs is not prior art under 35 U.S.C. § 102(a). Therefore, Dr. Lowman's invalidity contention based on Jacobs is wrong on its face.

5. It is also my understanding that a reference is not prior art under 102(a) if the inventors can establish that reduction to practice occurred prior to the effective date of the reference. It is my understanding that inventors can establish earlier reduction to practice by submitting a declaration to "swear behind" the reference. I have reviewed Dr. Sawhney's and Dr. Edelman's Combined Declaration and related exhibit. I have also reviewed Dr. Pathak's Declaration and related exhibit. I understand "SprayGel" to be a hydrogel composition, using precursors including a biocompatible PEG portion, within the scope of the method claims of the patents and that "SprayGel" was tested for biocompatibility using standard histological techniques and determined to be biocompatible because it produced a minimal inflammatory response. I have education and experience enough to understand a histology report of "minimal inflammatory response" supporting biocompatibility of a hydrogel without having extensive experience in actually conducting and evaluating histological studies. I can understand and rely on the results of others with particular expertise. I can also understand that a report of "poor biocompatibility" for a hydrogel would not mean the hydrogel is biocompatible because such a conclusion would render the term "biocompatible" meaningless. I also understand that biocompatibility as used in

the patents is not defined by regulatory approval. Dr. Sawhney's and Dr. Edelman's Combined Declaration states at Paragraph 4:

> Before Jacobs and Dunn, we or others at our direction carried out histological testing to show that SprayGel produced minimal inflammatory response which is the basis for the statement in Dunn as to product safety. Dunn evidences conception and reduction to practice of "SprayGel" at least as early as February 2001, which is the publication date of Dunn. However, Dunn evidences an earlier conception and reduction to practice date of at least March 27, 2000 (which is the submission date) or September 20, 2000 (which is the acceptance date of Dunn prior to publication). The reduction to practice of the invention occurred in the United States. Dunn reports on another pre-clinical evaluation of "SprayGel" commissioned by Confluent. Drs. Dunn, Lyman, and Campbell were the team of doctors involved with that pre-clinical evaluation of SprayGel. We assembled, directed, and supervised the team of doctors that performed the pre-clinical evaluation of SprayGel that is described in Dunn. Together, and without help from anyone other than individuals working under our direction and supervision, we developed the protocol for the pre-clinical evaluation described in Dunn. We were the sole source of the SprayGel raw materials chemistry and formulation of pre-cursor solutions, that were used in the pre-clinical evaluation conducted by Drs. Dunn, Lyman, and Campbell. Drs. Dunn, Lyman and Campbell were working under our direction as pre-clinical evaluators and were not involved in the conception of the subject matter disclosed in Dunn. Accordingly, the study described by Dunn was done on our behalf, was published on our behalf, and is our own work.

6. Dr. Pathak's Declaration states at Paragraph 2:

> I have reviewed U.S. Patent No. 7,009,034. I have also reviewed the document attached hereto as Exhibit A, entitled "Evaluation of the SprayGel™ adhesion barrier in the rat cecum abrasion and rabbit uterine horn adhesion models" and the description of SprayGel at page 412. Exhibit A evidences reduction to practice of the subject matter claimed in claim 10 of U.S. Patent No. 7,009,034 at least as early as February 2001.

7. In my opinion, these unrefuted facts establish that claim 10 of the '034 patent is entitled to a priority date of least February 2001. Accordingly, in my opinion, Jacobs is not prior art under 35 U.S.C. § 102(a). Therefore, Dr. Lowman's invalidity contention based on Jacobs is wrong on its face.

I HEREBY DECLARE under penalty of perjury that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. §1001.

Date: 2/21/2018

Jimmy Mays

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC, Plaintiffs, v. HyperBranch Medical Technology, Inc., Defendant.	Civil Action No. 15-819 (LPS) (CJB)

DECLARATION OF DR. AMARPREET S. SAWHNEY

I, Amarpreet S. Sawhney, Ph.D., declare as follows:

1. My full name is Amarpreet S. Sawhney. I am currently Chairman, President and CEO of Ocular Therapeutix, Inc. I am a named inventor on U.S. Patent No. 7,009,034 (The '034 patent) owned by Incept, L.L.C. The other named inventors of the '034 patent are Dr. Peter G. Edelman and Dr. Chandrashekhar P. Pathak. The inventions claimed in the '034 patent derive directly from the work of Drs. Edelman, Pathak, and me.

2. From August 1998 to August 2006, I was Co-founder, President and CEO of Confluent Surgical, Inc. From 1998 to 2001, Dr. Edelman was employed by Confluent. Our duties and responsibilities at Confluent included the design and development of products, including a product called "SprayGel."

3. I have been informed that HyperBranch Medical Technology, Inc. ("HyperBranch") asserts that claim 10 of the '034 patent is unpatentable in light of "SprayGel™ as New Intraperitoneal Adhesion Prevention Method for Use in Laparoscopy and Laparotomy,"

VR Jacobs, E Lehmann-Willenbrock, M Kiechle, L Mettler, ISGE 10 Convention, Chicago March 2001. I will refer to this document as "Jacobs" hereafter. Jacobs is attached hereto as Exhibit A.

4. The authors of Jacobs – Drs. Jacobs, Lehmann-Willenbrock, and Mettler – were a team of doctors commissioned by Confluent to conduct a clinical evaluation of SprayGel in Europe for adhesion prevention. As President and CEO, I assembled, directed, and supervised that team of doctors that performed the clinical evaluation of SprayGel. I developed the protocol for the clinical evaluation of SprayGel performed by Drs. Jacobs, Lehmann-Willenbrock, and Mettler. To the extent that others contributed to the design and analysis of the clinical evaluation, they did so under my direction and supervision. I was the sole source of the SprayGel materials that were used in the clinical evaluation conducted by Drs. Jacobs, Lehmann-Willenbrock, and Mettler. Drs. Jacobs, Lehmann-Willenbrock, and Mettler were working under my direction as clinical evaluators and were not involved in the conception of the subject matter disclosed in Jacobs. Accordingly, the study described by Jacobs was done on our behalf, was published on our behalf, and is our own work.

I HEREBY DECLARE under penalty of perjury that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. §1001.

Date: 2/18/18

Amarpreet W. Sawhney

Exhibit A to Sawhney Declaration

ISGE 10, Chicago March 2001

SprayGel™ as New Intraperitoneal Adhesion Prevention Method for Use in Laparoscopy and Laparotomy

VR Jacobs [1, 2], E Lehmann-Willenbrock [1], M Kiechle [1,2], L Mettler [1]

[1] Frauenklinik (OB/GYN), Chr.-Albrechts-Univ., Kiel, [2] Frauenklinik (OB/GYN), Technical Univ., Munich, Germany

Objective:

Previous intraperitoneal **adhesion prevention methods have not proven to be sufficient and effective enough**. Confluent Surgical Inc., Waltham, MA, USA, has developed a new adhesion prevention method, named **SprayGel™** and we present our clinical experience with its application.

Methods:

A **two component fluid**, based on **polyethylene glycol (PEG)** has been developed which forms immediately after application on the tissue surface a hydrogel film through **rapid polymerization**. **SprayGel™** is used with a pressure-balanced sprayer with which it can be applied at exact defined areas inside the abdomen. It **seals** mechanically the **tissue and** even **small bleedings** instantly. The anti-adhesion film is **slowly hydrolyzed** within several days (Fig. 1) and eliminated through the kidneys. Although **SprayGel™** is transparent, **methylene blue** has been **added for better visualization** of application.

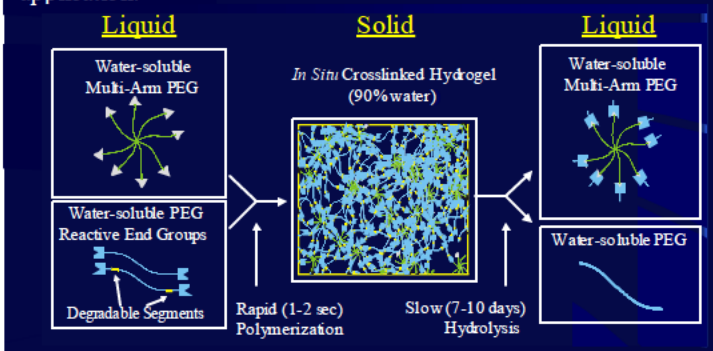


Fig. 1. Polymerization and hydrolysis of PEG.

Results:

After **animal studies showed** the intended **effect** (Fig. 2) and assured product safety, **SprayGel™ is under evaluation** in an ongoing, **randomized controlled study** to **prevent uterine adhesions** after laparoscopic and open myomectomy in over 60 patients up to now in Kiel, Germany, and Bordeaux, France. Enrollment has recently been completed. Application of **SprayGel™** is fast and easy. With the **bent tip** even **areas difficult to reach are completely covered** with the hydrogel. Although **results are preliminary** study patients so far showed **less intraabdominal adhesions than expected**.

All **equipment worked reliable** under clinical conditions; **no serious adverse event** was noted so far. **Advantages of PEG application** for adhesion prevention are: rapid in-situ polymerization with **no heat evolved**, **no external energy** (e.g. heat, light) required, **biocompatible**, **flexible** hydrogel layer, remains intact for about a week, **completely eliminated** through kidneys and can be used in laparoscopy and open surgery.

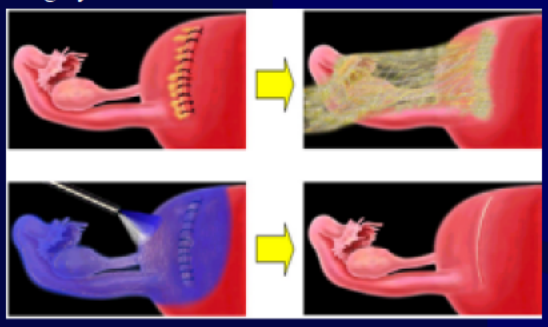
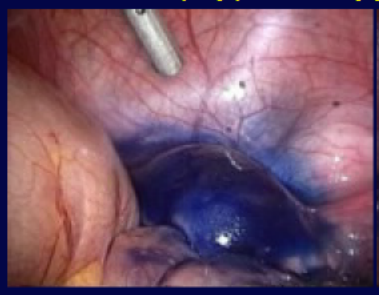


Fig. 2. Intended effect: without SprayGel: adhesions (top), after application: none (bottom).



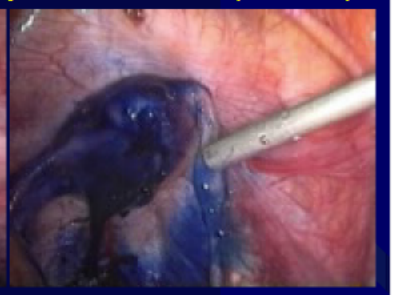


Fig. 3. SprayGel covering anterior wall and Fig. 4. posterior wall of uterus.

Conclusion:

SprayGel ™ offers an **interesting alternative to existing adhesion prevention systems** and can be used in either laparoscopy or laparotomy. Application is easy, fast and sufficient. **Results** of the ongoing study **have to confirm its advantages above established adhesion prevention methods**.

References

Dunn R, Lymen MD, Edelman PG, Campbell PK: Evaluation of the SprayGel™ adhesion barrier in the rat cecum abrasion and rabbit uterine horn adhesion models. Fertil Steril 2001;75(2):411-416.

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC, Plaintiffs, v. HyperBranch Medical Technology, Inc., Defendant.	Civil Action No. 15-819 (LPS) (CJB)

DECLARATION OF DR. AMARPREET S. SAWHNEY AND DR. PETER G. EDELMAN

We, Amarpreet S. Sawhney, Ph.D., and Peter G, Edelman, Ph.D., hereby declare as follows:

1. We are named inventors on U.S. Patent No. 7,009,034.

2. The document attached as Exhibit A is a copy of a true and accurate document that was in existence at least as early as February 2001 or before. The document is entitled "Evaluation of the SprayGel™ adhesion barrier in the rat cecum abrasion and rabbit uterine horn adhesion models." The document is authored by Dr. Edelman, Dr. Randall Dunn, Michelle D. Lyman, and Dr. Patrick K. Campbell. The document will be referred to as "Dunn" hereafter. Dunn identifies that it was received by the Journal *Fertility and Sterility* on March 27, 2000 and accepted on September 20, 2000. Dunn states that the evaluations were supported by Confluent Surgical, Inc.

3. Dunn describes SprayGel as follows:

> The SprayGel adhesion barrier system consists of two synthetic modified polyethylene glycol (PEG) solutions (referred to as precursors) that polymerize rapidly when mixed at the site of application to form a biocompatible absorbable hydrogel. The PEG molecules in the precursor solutions have complementary end functional groups (amines on one end and N-hydroxysuccinimide esters on the other) that react with each other to cause polymerization, which is complete within

> seconds with no heat evolution. The precursors are sprayed onto tissues by using an air-assisted sprayer (Figure 1) that can be used in both laproscopic and open surgical procedures. The formed hydrogel remains intact and adherent to underlying tissues for 5-6 days, then breaks down into water-soluble PEG molecules through hydrolysis. Clearance of PEG from the body is well documented and understood and occurs primarily through the kidneys (14, 15). Methylene blue was added to one of the precursor solutions to aid in visualization of the SprayGel deposition.

4. Jacobs includes a similar description of SprayGel and also references Dunn. Jacobs also states that before the adhesion prevention study, "animal studies showed the intended effect (Fig. 2) and assured product safety." Before Jacobs and Dunn, we or others at our direction carried out histological testing to show that SprayGel produced minimal inflammatory response which is the basis for the statement in Dunn as to product safety. Dunn evidences conception and reduction to practice of "SprayGel" at least as early as February 2001, which is the publication date of Dunn. However, Dunn evidences an earlier conception and reduction to practice date of at least March 27, 2000 (which is the submission date) or September 20, 2000 (which is the acceptance date of Dunn prior to publication). The reduction to practice of the invention occurred in the United States. Dunn reports on another clinical evaluation of "SprayGel" commissioned by Confluent. Drs. Dunn, Lyman, and Campbell were the team of doctors involved with that pre-clinical evaluation of SprayGel. We assembled, directed, and supervised the team of doctors that performed the pre-clinical evaluation of SprayGel that is described in Dunn. Together, and without help from anyone other than individuals working under our direction and supervision, we developed the protocol for the clinical evaluation described in Dunn. We were the sole source of the SprayGel raw materials that were used in the clinical evaluation conducted by Drs. Dunn, Lyman, and Campbell. Drs. Dunn, Lyman and Campbell were working under our direction as clinical evaluators and were not involved in the conception of the subject matter disclosed in Dunn. Accordingly, the study described by Dunn was done on our behalf, was published on our behalf, and is our own work.

I HEREBY DECLARE under penalty of perjury that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. §1001.

Date: 2/18/18

Amarpreet W. Sawhney

Date: 20 Feb 2018

Peter G. Edelman

Exhibit A to Combined Sawhney and Pathak Declaration

FERTILITY AND STERILITY®
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TECHNIQUES AND INSTRUMENTATION

Evaluation of the SprayGel™ adhesion barrier in the rat cecum abrasion and rabbit uterine horn adhesion models

Randall Dunn, M.D.,[a] *Michelle D. Lyman, B.S.,*[b] *Peter G. Edelman, Ph.D.,*[b] *and Patrick K. Campbell, Ph.D.*[b]

OB/GYN Associates, PA, Houston, Texas; and Confluent Surgical, Inc., Waltham, Massachusetts

Objective: To evaluate the efficacy of a new adhesion barrier in the prevention of postoperative adhesion formation.

Design: A double-blind controlled study of the efficacy of SprayGel in reducing postoperative adhesion formation in two animal models.

Setting: Animal care facility of a contract testing laboratory.

Animal(s): Sixteen Sprague-Dawley male rats were randomly allocated into two groups in the cecum abrasion model. Twenty New Zealand white female rabbits were randomly allocated into two groups in the uterine horn abrasion model.

Intervention(s): In the rat model, the cecum was abraded with gauze and the abdominal wall was abraded with a scalpel. Treated animals received SprayGel coating on injured surfaces; control animals received no treatment. In the rabbit model, uterine horns were abraded with a scalpel. Treated animals received SprayGel coating on injured surfaces; control animals received no treatment.

Main Outcome Measure(s): Postoperative adhesion formation.

Result(s): In the rat model, SprayGel was found to significantly reduce the incidence of adhesions, which formed in 7 of 8 control rats compared with 1 of 8 treated rats. In the rabbit model, SprayGel was found to significantly reduce both the extent and severity of adhesions.

Conclusion(s): Application of SprayGel in two animal models reduced formation of postoperative adhesions. Further investigation in large animal and clinical settings is warranted. (Fertil Steril® 2001;75:411–6. ©2001 by American Society for Reproductive Medicine.)

Key Words: Adhesion prevention, preclinical models, gynecologic surgery, adhesion barrier

Adhesions are abnormal fibrous bands between adjacent parts or structures of the body. They are typically caused by inflammation or surgical trauma. Adhesions after gynecologic surgery are believed to be a major cause of chronic or recurrent pain in a substantial number of women and are considered to be a major cause of infertility (1). Intestinal obstruction, which often requires surgical intervention, is the most serious complication of intraperitoneal adhesions. The overall mortality rate among patients hospitalized with intestinal obstruction was reported to be 11.4% in one large prospective study (2). The most common cause of adhesions is previous surgery that may lead to new adhesions or adhesion reformation at the site of previous adhesiolysis (3).

Adhesions form because the normal wound-healing process in response to tissue injury or local inflammation goes awry. After peritoneal tissue has been traumatized in a surgical procedure, fibrin deposition is evident within 12 hours. New mesothelium begins to develop 2 to 3 days after the initial injury. Remesothelialization is normally complete within 7 to 9 days (4, 5).

Researchers have attempted to address the problem of adhesions by systemic administration of antibiotics, antihistamines, and corticosteroids. All of these agents have side effects, and their relative abilities to prevent or reduce adhesion formation have been largely theoretical rather than clinically substantiated. Local administration of dextran, tissue plasminogen

Received March 27, 2000; revised and accepted September 20, 2000.

Supported by Confluent Surgical, Inc., Waltham, Massachusetts.

Reprint requests: Randall Dunn, M.D., OB/GYN Associates, PA, 7550 Fannin, Houston, Texas 77054 (FAX: 713-512-7829; E-mail: obgynassociates.com).

[a] OB/GYN Associates, PA.

[b] Confluent Surgical, Inc..

0015-0282/01/$20.00
PII S0015-0282(00)01677-0

activator, heparin, nonsteroidal antiinflammatory drugs, and hydrocortisone also have been demonstrated to have undesired side effects on wound healing, fluid balance, or hemostasis without reliable success in preventing formation of adhesions (6–9).

Other attempts to reduce adhesion formation have focused on use of physical barriers (10–13). Some barrier materials, including polytetrafluoroethylene, hyaluronic acid–based products, and oxidized regenerated cellulose materials, were met with enthusiasm when first released for use in gynecologic surgery. However, reports of their performance have been mixed, and none of these classes of products have produced unequivocal results. Technical difficulties associated with these products include difficult preparation and application, the need for absolute hemostasis, insufficient pliability, required product fixation techniques, incompatibility with laparoscopic surgical procedures, and the need for removal of permanent barrier materials.

An absorbable hydrogel film, SprayGel (Confluent Surgical, Inc., Waltham, MA), was developed as a postsurgical adhesion barrier. This synthetic hydrogel film is formed in situ by spraying it onto injured sites prone to adhesion formation. The film adheres to tissue, and after several days, it is hydrolyzed and absorbed as water-soluble components that undergo renal excretion. In this study, blinded to the surgeon and the adhesion scorer, we evaluated the efficacy of SprayGel in reducing postsurgical formation of adhesions in a rat cecum abrasion model and a rabbit uterine horn model.

MATERIALS AND METHODS

The rat study protocol was approved by the Animal Care Committee of New England Medical Center, Boston, Massachusetts; the rabbit study protocol was approved by the Animal Care Committee of North American Science Associates, Northwood, Ohio.

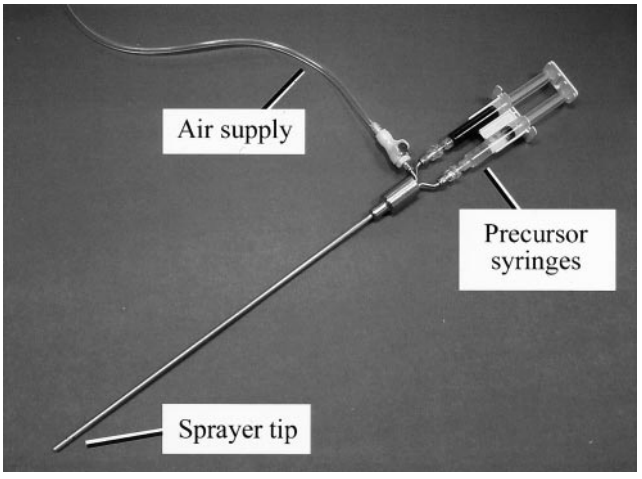
SprayGel

The SprayGel adhesion barrier system consists of two synthetic modified polyethylene glycol (PEG) solutions (referred to as precursors) that polymerize rapidly when mixed at the site of application to form a biocompatible absorbable hydrogel. The PEG molecules in the precursor solutions have complementary end functional groups (amines on one end and *N*-hydroxysuccinimide esters on the other) that react with each other to cause polymerization, which is complete within seconds with no heat evolution. The precursors are sprayed onto tissues by using an air-assisted sprayer (Figure 1) that can be used in both laparoscopic and open surgical procedures. The formed hydrogel remains intact and adherent to underlying tissues for 5–6 days, then breaks down into water-soluble PEG molecules through hydrolysis. Clearance of PEG from the body is well documented and understood and occurs primarily through the kidneys (14, 15).

Methylene blue was added to one of the precursor solutions to aid in visualization of the SprayGel deposition. The colorant diffuses out of the hydrogel film within hours after application and is excreted from the body.

FIGURE 1

The SprayGel adhesion barrier applicator. The two precursor solutions are injected through the device, where they are atomized at the tip. The applicator is designed for open and laparoscopic use.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

Rat Adhesion Barrier Efficacy Model

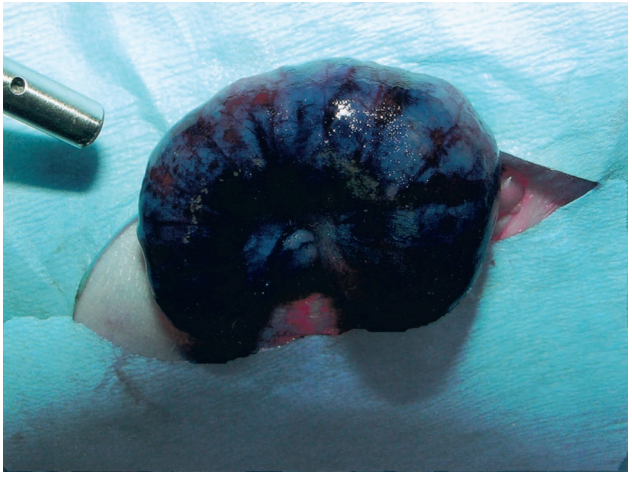
Animal Preparation and Operative Procedure

Sixteen male Sprague-Dawley rats weighing 250–350 g (Charles River Laboratories, Wilmington, MA) were anesthetized with a cocktail of ketamine (66 mg/mL) and xylazine (9 mg/mL), 2.25 mL/kg given intramuscularly. The abdominal area was shaved and prepared for aseptic surgery. A midline laparotomy was performed. The cecum was identified and exteriorized, and the lateral and ventral surfaces were abraded by using dry sterile gauze until petechial hemorrhage was observed. The cecal vascular arcade on the same side was interrupted by using bipolar electrocautery. A 1×2 cm area of the abdominal side wall opposite the injured cecum was scraped to the point of hemorrhage by using a no. 10 scalpel blade. Brief pressure with surgical gauze was used to control active bleeding before proceeding.

After injury, animals were randomly allocated to the treatment ($n=8$) or control ($n=8$) group. In control animals, the cecum was repositioned in the peritoneal cavity with no additional interventions, the peritoneum and muscle wall were closed by using 3-0 nylon suture, and the skin was closed by using 4-0 silk suture (Ethicon, Somerville, NJ). In animals in the treatment group, SprayGel was applied to the injured cecum and sidewall surfaces (Figure 2). Sufficient hydrogel was applied to make the underlying vascular struc-

FIGURE 2

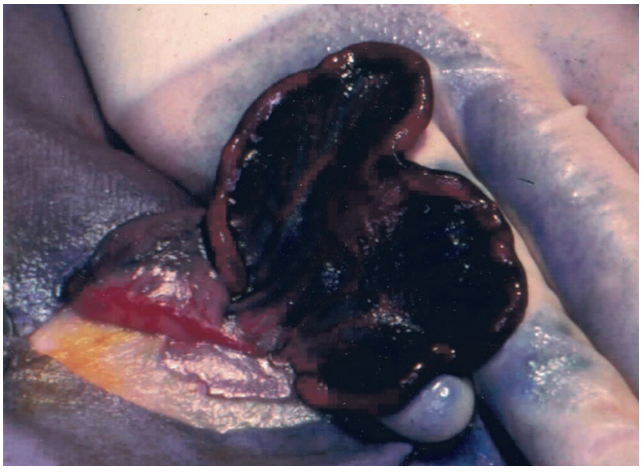
Rat cecum treated with SprayGel adhesion barrier. Methylene blue allows easy identification of all coated areas.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

FIGURE 3

Application of SprayGel adhesion barrier to rabbit uterine horn. Methylene blue allows assessment of barrier location and thickness.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

tures on the tissues difficult to visualize (gel thickness, 1–2 mm). After application, the hydrogel was wetted with normal saline (Abbott, Abbott Park, IL) before repositioning within the peritoneal cavity. Treated animals were then closed as described above. Previous studies using the same model produced cecum-to-sidewall adhesions in an average of 86% of control animals.

Postoperative Evaluation

The rats were euthanized after 12 days by using carbon dioxide asphyxiation. A blinded observer evaluated formation of adhesions between the sidewall and cecum. The presence or absence of adhesions at each site was noted, and extent of adhesion coverage was scored as follows: 0, clean, no adhesions; 1, adhesions on $<$ 50% of the cecum; and 2, adhesions on 50%–100% of the cecum. Adhesion severity was scored as 0, clean, no adhesions; 1, filmy adhesions; and 2, dense vascular adhesions.

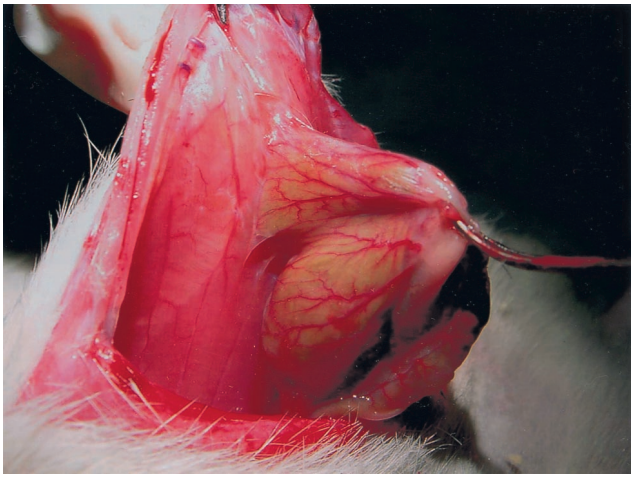
Rabbit Adhesion Barrier Efficacy Model

Animal Preparation and Operative Procedure

Twenty female New Zealand white rabbits weighing 2.4–3.1 kg (Myrtle's Rabbitry, Inc., Thompson Station, TN) were anesthetized by using a cocktail of ketamine (34 mg/kg) and xylazine (5 mg/kg), 0.6 mL/kg given intramuscularly. After administration of the anesthetic, an analgesic (buprenorphine) was injected subcutaneously at a dose of 0.02 mg/kg. The animals were placed on isoflurane/oxygen inhalation for maintenance of anesthesia. Animals were placed in the dorsal recumbent position, and the entire ventral abdominal area was prepared and draped in a sterile manner. An incision approximately 3 cm in length was made in the caudal ventral midline into the peritoneal cavity, and the uterine horns were exteriorized. The middle third segment of the serosa of both uterine horns was abraded by using the sharp edge of a no. 10 scalpel blade; a new blade was used for each animal. The edge of the blade was rubbed across the uterine horn to remove the serosa and to induce wounds with petechial hemorrhage. The affected areas were approximately 1 cm

FIGURE 4

Adhesion of cecum to sidewall in a control animal in the rat cecum abrasion model.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

from the uterine bifurcation for a length of 5 cm. The surgeon performing the injury was blinded to the animal's eventual group assignment.

After injury, animals were randomly allocated to the control group (n=10), which received no additional intervention, or to the treatment group (n=10), which received SprayGel application (Figure 3). During SprayGel application, several locations of punctate bleeding often persisted on each horn and continued even after barrier application. After application of SprayGel on the dorsal surface, saline was used to wet the hydrogel surface; application and wetting were repeated on the ventral surface. The horns were then repositioned in the peritoneal cavity; the musculoperitoneal layers of the incisions were closed by using 4-0 Vicryl suture and the skin was closed by using 4-0 nylon (Ethicon). Animals were monitored for recovery from anesthesia and were observed daily for signs of illness or injury. Historically, this model has produced adhesions in more than 80% of control animals.

Postoperative Evaluation

At 15 days, the rabbits were euthanized by intravenous injection of a sodium pentobarbital–based solution. A blinded observer opened the peritoneal cavity and scored the extent of adhesions by using the following scale: 0, clean, no adhesions; 1, adhesions on up to 25% of the injured area; 2, adhesions on 25%–50% of the injured area; and 3, greater than 50% adhesion involvement. Adhesion severity was scored as follows: 0, clean, no adhesions; 0.5, some resistance (slight force required); and 1, moderate resistance or blunt dissection.

Statistical Analysis

For both the rat and rabbit study data, a χ^2 test was used to compare the rate of adhesion incidence between the treatment and control groups. The Wilcoxon signed-rank test for nonparametric data was used to compare adhesion extent and severity scores between the treatment and control groups (SPSS software, version 9.0; SPSS, Inc., Chicago, IL). $P<.05$ was considered to be statistically significant.

RESULTS

Rat Cecum Abrasion Model

All animals survived the procedure, and none were excluded from the study. The adhesion extent and severity scores in the control and treated rats are shown in Table 1. At harvest, 7 of 8 control animals and 1 of 8 treated animals had adhesions between the cecum and sidewall, which represented a 86% reduction in incidence ($P=.034$). Treated animals had significantly lower extent scores than control animals (0 of 8 treated rats and 6 of 8 control rats had adhesions on $>$ 50% of the cecum; $P=.003$) (Figure 4). Adhesion severity was also significantly reduced in treatment group; 1 of 8 treated rats had dense vascular adhesions compared with 4 of 8 control rats ($P=.015$).

TABLE 1

Adhesion extent and severity scores in the rat cecum abrasion model.[a]

	Adhesion extent		Adhesion severity	
Rat	Control	Treated	Control	Treated
1	2	1	1	2
2	2	0	2	0
3	1	0	1	0
4	2	0	2	0
5	0	0	0	0
6	2	0	2	0
7	2	0	2	0
8	2	0	1	0
P value[b]		.003		.015

[a] See Materials and Methods for explanation of scoring system.
[b] Wilcoxon signed-rank test ($P<.05$ statistically significant).

Dunn. Evaluation of SprayGel Adhesion barrier. Fertil Steril 2001.

Rabbit Uterine Horn Model

All animals survived the procedures, and no animals were excluded. In general, the animals remained in good health for the duration of the study. The animals maintained or gained body weight. Occasional incidence of reduced fecal output, diarrhea, and incision problems (wound exudate, removed sutures) were noted in both treated and control animals; no trends were observed in either group.

Adhesion extent and severity scores for the control and treated rabbits are shown in Table 2. Treated animals had

TABLE 2

Adhesion extent and severity scores in the rabbit uterine horn model.[a]

	Adhesion extent		Adhesion severity	
Rabbit	Control	Treated	Control	Treated
1	3	3	1	1
2	3	1	1	1
3	3	1	1	1
4	3	0	1	0
5	3	3	1	1
6	3	1	1	0.5
7	3	1	1	0.5
8	2	1	1	0.5
9	1	1	1	0.5
10	3	1	1	0.5
P value[b]		.007		.023

[a] See Materials and Methods for explanation of scoring system.
[b] Wilcoxon signed-rank test ($P<.05$ statistically significant).

Dunn. Evaluation of SprayGel Adhesion barrier. Fertil Steril 2001.

significantly lower adhesion extent scores than control animals (2 of 10 treated rabbits and 8 of 10 control rabbits had > 50% uterine horn involvement in adhesions; $P=.007$). Adhesion severity also differed significantly between the groups; 4 of 10 treated rabbits and 10 of 10 control rabbits had adhesions with moderate resistance ($P=.023$).

DISCUSSION

Use of physical barriers between injured tissues has long been proposed as a method to prevent postsurgical adhesion formation (10–13). As general requirements for an adhesion barrier, Wiseman (16) proposed that it should not interfere with wound healing, should not potentiate infection, should not evoke fibrosis, should be usable by an endoscopic technique, should remain efficacious in the presence of blood, and should be degradable.

Most barriers developed to date are liquids, preformed gels, or solid sheets. Liquid solutions diffusely coat the abdominal and pelvic organs but are often cleared from the site of application before the requisite window of therapeutic efficacy, which has been proposed to be at least 3 days (9). Preformed gels, such as ferric hyaluronate hydrogels, flow and coat organs. Their clearance from the abdominal cavity is slower than that of solutions; however, their adherence to locally traumatized tissue is not strong. Preformed films, such as those made from hyaluronic acid and oxidized regenerated cellulose, provide a more durable local presence, but only if they are prevented from migrating from the site of application. In addition, the ease of use of these sheets and films in endoscopic procedures and their prolonged local adherence are not guaranteed. Thus, most currently available adhesion barriers lack one or more of the key characteristics outlined by Wiseman.

In contrast, the SprayGel adhesion barrier possesses most of the key characteristics required for an ideal adhesion barrier. PEG is a poor food source for bacteria because of its nonbiological origin. Thus, along with the rapid barrier absorption rate, SprayGel does not lend itself readily to the promotion or potentiation of bacterial infection. The synthetic chemistry has been optimized to react rapidly on the tissue to allow for easy deposition and visualization. Since the material transforms from a liquid to a solid hydrogel, it can tenaciously adhere to wet tissues and protect these tissues through the critical repair period. The absorption profile of this material has been tailored to ensure its presence during the critical first 6–7 days of healing. From the time of application to the time of absorption, the hydrogel remains adherent to the surface on which it is applied. The hydrogel barrier itself is more than 90% water at application. Because of this high water content the adhesion barrier presents a highly lubricious and biocompatible interface with the surrounding tissue.

Application of SprayGel to the rat cecum and sidewall was straightforward and took only minutes, since the geometry can be easily manipulated and visualized. Material coverage and thickness were simple to gauge because of the colorant added to the hydrogel. Wetting of the hydrogel surface was performed in all treated animals before closing of the wound to provide a lubricious hydrogel surface. With a hydrogel thickness of 1–2 mm, the saline did not come into contact with the injured tissue surface. Saline running off the gel onto other peritoneal tissues was unlikely to affect the study outcome; Ringer's lactate solution has been shown to be ineffective at preventing adhesions in both rat and rabbit adhesion models (17, 18).

The uterine horns in the rabbit were smaller (often < 5 mm diameter), thus making application of SprayGel more challenging. The increased difficulty in application to a small structure, along with the punctate bleeding that persisted even after barrier application, are thought to account for the differences in adhesion incidence data between the two models. Rat and rabbit adhesion models have historically been accepted as adequate preclinical predictors of clinical efficacy. However, preclinical models with larger organ sizes, weights and forces, and relevant surgical procedures may be better predictors of efficacy in humans. Thus, further studies in a large animal adhesion formation model that mimics the human surgical environment have been undertaken before human clinical studies are begun.

Acknowledgments Confluent Surgical, Inc., thanks Jim Titus for assistance in the surgical procedures; Ogan Gurel, M.D., for expert critical review of the manuscript; and Erin R. Campbell, Ed.D., for statistical assistance.

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Exhibit C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC, Plaintiffs, v. HyperBranch Medical Technology, Inc., Defendant.	Civil Action No. 15-819 (LPS) (CJB)

DECLARATION OF DR. CHANDRASHEKBAR P. PATHAK

I, Chandrashekbar P. Pathak, Ph.D., hereby declare as follows:

1. I am a named inventor on U.S. Patent No. 7,009,034.

2. I have reviewed U.S. Patent No. 7,009,034. I have also reviewed the document attached hereto as Exhibit A, entitled "Evaluation of the SprayGel™ adhesion barrier in the rat cecum abrasion and rabbit uterine horn adhesion models" and the description of SprayGel at page 412. Exhibit A evidences reduction to practice of the subject matter claimed in claim 10 of U.S. Patent No. 7,009,034 at least as early as February 2001. The reduction to practice of the invention occurred in the United States.

I HEREBY DECLARE under penalty of perjury that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and imprisonment, or both, under 18 U.S.C. §1001.

Date: Feb 20 2018

Chandrashekbar P. Pathak

Exhibit A to Pathak Declaration

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TECHNIQUES AND INSTRUMENTATION

Evaluation of the SprayGel™ adhesion barrier in the rat cecum abrasion and rabbit uterine horn adhesion models

Randall Dunn, M.D.,[a] *Michelle D. Lyman, B.S.,*[b] *Peter G. Edelman, Ph.D.,*[b] *and Patrick K. Campbell, Ph.D.*[b]

OB/GYN Associates, PA, Houston, Texas; and Confluent Surgical, Inc., Waltham, Massachusetts

Objective: To evaluate the efficacy of a new adhesion barrier in the prevention of postoperative adhesion formation.

Design: A double-blind controlled study of the efficacy of SprayGel in reducing postoperative adhesion formation in two animal models.

Setting: Animal care facility of a contract testing laboratory.

Animal(s): Sixteen Sprague-Dawley male rats were randomly allocated into two groups in the cecum abrasion model. Twenty New Zealand white female rabbits were randomly allocated into two groups in the uterine horn abrasion model.

Intervention(s): In the rat model, the cecum was abraded with gauze and the abdominal wall was abraded with a scalpel. Treated animals received SprayGel coating on injured surfaces; control animals received no treatment. In the rabbit model, uterine horns were abraded with a scalpel. Treated animals received SprayGel coating on injured surfaces; control animals received no treatment.

Main Outcome Measure(s): Postoperative adhesion formation.

Result(s): In the rat model, SprayGel was found to significantly reduce the incidence of adhesions, which formed in 7 of 8 control rats compared with 1 of 8 treated rats. In the rabbit model, SprayGel was found to significantly reduce both the extent and severity of adhesions.

Conclusion(s): Application of SprayGel in two animal models reduced formation of postoperative adhesions. Further investigation in large animal and clinical settings is warranted. (Fertil Steril® 2001;75:411–6. ©2001 by American Society for Reproductive Medicine.)

Key Words: Adhesion prevention, preclinical models, gynecologic surgery, adhesion barrier

Adhesions are abnormal fibrous bands between adjacent parts or structures of the body. They are typically caused by inflammation or surgical trauma. Adhesions after gynecologic surgery are believed to be a major cause of chronic or recurrent pain in a substantial number of women and are considered to be a major cause of infertility (1). Intestinal obstruction, which often requires surgical intervention, is the most serious complication of intraperitoneal adhesions. The overall mortality rate among patients hospitalized with intestinal obstruction was reported to be 11.4% in one large prospective study (2). The most common cause of adhesions is previous surgery that may lead to new adhesions or adhesion reformation at the site of previous adhesiolysis (3).

Adhesions form because the normal wound-healing process in response to tissue injury or local inflammation goes awry. After peritoneal tissue has been traumatized in a surgical procedure, fibrin deposition is evident within 12 hours. New mesothelium begins to develop 2 to 3 days after the initial injury. Remesothelialization is normally complete within 7 to 9 days (4, 5).

Researchers have attempted to address the problem of adhesions by systemic administration of antibiotics, antihistamines, and corticosteroids. All of these agents have side effects, and their relative abilities to prevent or reduce adhesion formation have been largely theoretical rather than clinically substantiated. Local administration of dextran, tissue plasminogen

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Supported by Confluent Surgical, Inc., Waltham, Massachusetts.

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activator, heparin, nonsteroidal antiinflammatory drugs, and hydrocortisone also have been demonstrated to have undesired side effects on wound healing, fluid balance, or hemostasis without reliable success in preventing formation of adhesions (6–9).

Other attempts to reduce adhesion formation have focused on use of physical barriers (10–13). Some barrier materials, including polytetrafluoroethylene, hyaluronic acid–based products, and oxidized regenerated cellulose materials, were met with enthusiasm when first released for use in gynecologic surgery. However, reports of their performance have been mixed, and none of these classes of products have produced unequivocal results. Technical difficulties associated with these products include difficult preparation and application, the need for absolute hemostasis, insufficient pliability, required product fixation techniques, incompatibility with laparoscopic surgical procedures, and the need for removal of permanent barrier materials.

An absorbable hydrogel film, SprayGel (Confluent Surgical, Inc., Waltham, MA), was developed as a postsurgical adhesion barrier. This synthetic hydrogel film is formed in situ by spraying it onto injured sites prone to adhesion formation. The film adheres to tissue, and after several days, it is hydrolyzed and absorbed as water-soluble components that undergo renal excretion. In this study, blinded to the surgeon and the adhesion scorer, we evaluated the efficacy of SprayGel in reducing postsurgical formation of adhesions in a rat cecum abrasion model and a rabbit uterine horn model.

MATERIALS AND METHODS

The rat study protocol was approved by the Animal Care Committee of New England Medical Center, Boston, Massachusetts; the rabbit study protocol was approved by the Animal Care Committee of North American Science Associates, Northwood, Ohio.

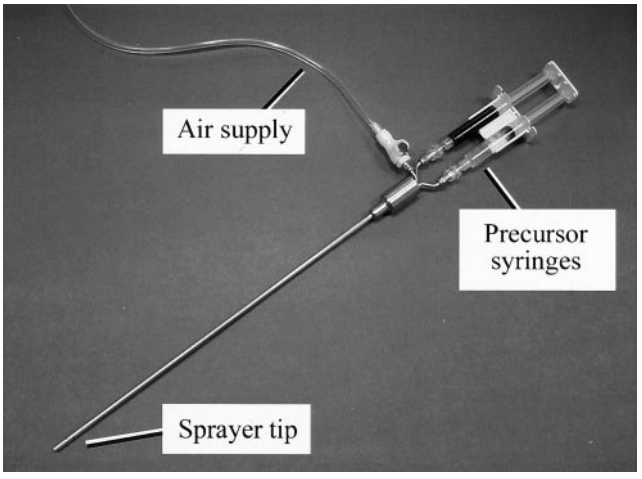
SprayGel

The SprayGel adhesion barrier system consists of two synthetic modified polyethylene glycol (PEG) solutions (referred to as precursors) that polymerize rapidly when mixed at the site of application to form a biocompatible absorbable hydrogel. The PEG molecules in the precursor solutions have complementary end functional groups (amines on one end and *N*-hydroxysuccinimide esters on the other) that react with each other to cause polymerization, which is complete within seconds with no heat evolution. The precursors are sprayed onto tissues by using an air-assisted sprayer (Figure 1) that can be used in both laparoscopic and open surgical procedures. The formed hydrogel remains intact and adherent to underlying tissues for 5–6 days, then breaks down into water-soluble PEG molecules through hydrolysis. Clearance of PEG from the body is well documented and understood and occurs primarily through the kidneys (14, 15).

Methylene blue was added to one of the precursor solutions to aid in visualization of the SprayGel deposition. The colorant diffuses out of the hydrogel film within hours after application and is excreted from the body.

FIGURE 1

The SprayGel adhesion barrier applicator. The two precursor solutions are injected through the device, where they are atomized at the tip. The applicator is designed for open and laparoscopic use.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

Rat Adhesion Barrier Efficacy Model

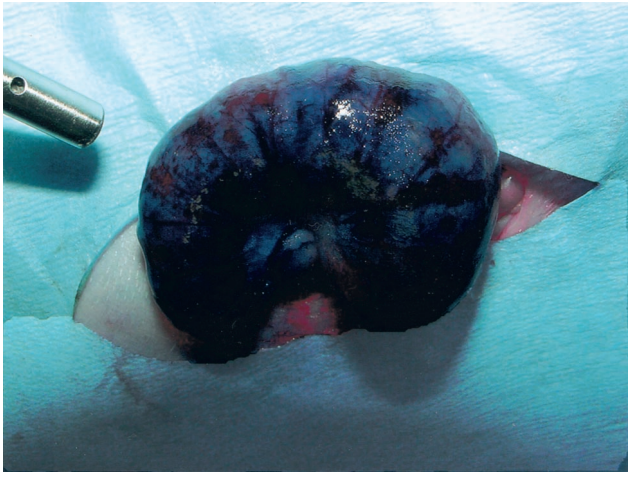
Animal Preparation and Operative Procedure

Sixteen male Sprague-Dawley rats weighing 250–350 g (Charles River Laboratories, Wilmington, MA) were anesthetized with a cocktail of ketamine (66 mg/mL) and xylazine (9 mg/mL), 2.25 mL/kg given intramuscularly. The abdominal area was shaved and prepared for aseptic surgery. A midline laparotomy was performed. The cecum was identified and exteriorized, and the lateral and ventral surfaces were abraded by using dry sterile gauze until petechial hemorrhage was observed. The cecal vascular arcade on the same side was interrupted by using bipolar electrocautery. A 1×2 cm area of the abdominal side wall opposite the injured cecum was scraped to the point of hemorrhage by using a no. 10 scalpel blade. Brief pressure with surgical gauze was used to control active bleeding before proceeding.

After injury, animals were randomly allocated to the treatment ($n=8$) or control ($n=8$) group. In control animals, the cecum was repositioned in the peritoneal cavity with no additional interventions, the peritoneum and muscle wall were closed by using 3-0 nylon suture, and the skin was closed by using 4-0 silk suture (Ethicon, Somerville, NJ). In animals in the treatment group, SprayGel was applied to the injured cecum and sidewall surfaces (Figure 2). Sufficient hydrogel was applied to make the underlying vascular struc-

FIGURE 2

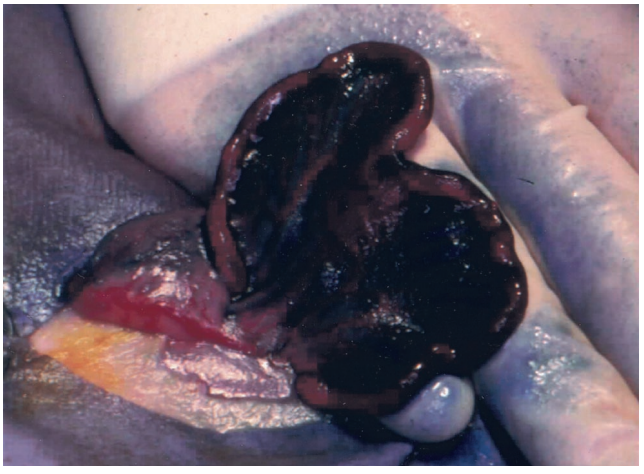
Rat cecum treated with SprayGel adhesion barrier. Methylene blue allows easy identification of all coated areas.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

FIGURE 3

Application of SprayGel adhesion barrier to rabbit uterine horn. Methylene blue allows assessment of barrier location and thickness.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

tures on the tissues difficult to visualize (gel thickness, 1–2 mm). After application, the hydrogel was wetted with normal saline (Abbott, Abbott Park, IL) before repositioning within the peritoneal cavity. Treated animals were then closed as described above. Previous studies using the same model produced cecum-to-sidewall adhesions in an average of 86% of control animals.

Postoperative Evaluation

The rats were euthanized after 12 days by using carbon dioxide asphyxiation. A blinded observer evaluated formation of adhesions between the sidewall and cecum. The presence or absence of adhesions at each site was noted, and extent of adhesion coverage was scored as follows: 0, clean, no adhesions; 1, adhesions on $<$ 50% of the cecum; and 2, adhesions on 50%–100% of the cecum. Adhesion severity was scored as 0, clean, no adhesions; 1, filmy adhesions; and 2, dense vascular adhesions.

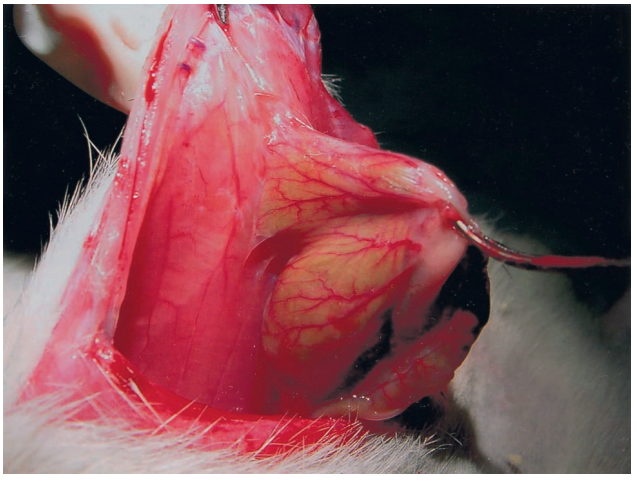
Rabbit Adhesion Barrier Efficacy Model

Animal Preparation and Operative Procedure

Twenty female New Zealand white rabbits weighing 2.4–3.1 kg (Myrtle's Rabbitry, Inc., Thompson Station, TN) were anesthetized by using a cocktail of ketamine (34 mg/kg) and xylazine (5 mg/kg), 0.6 mL/kg given intramuscularly. After administration of the anesthetic, an analgesic (buprenorphine) was injected subcutaneously at a dose of 0.02 mg/kg. The animals were placed on isoflurane/oxygen inhalation for maintenance of anesthesia. Animals were placed in the dorsal recumbent position, and the entire ventral abdominal area was prepared and draped in a sterile manner. An incision approximately 3 cm in length was made in the caudal ventral midline into the peritoneal cavity, and the uterine horns were exteriorized. The middle third segment of the serosa of both uterine horns was abraded by using the sharp edge of a no. 10 scalpel blade; a new blade was used for each animal. The edge of the blade was rubbed across the uterine horn to remove the serosa and to induce wounds with petechial hemorrhage. The affected areas were approximately 1 cm

FIGURE 4

Adhesion of cecum to sidewall in a control animal in the rat cecum abrasion model.



Dunn. Evaluation of SprayGel adhesion barrier. Fertil Steril 2001.

from the uterine bifurcation for a length of 5 cm. The surgeon performing the injury was blinded to the animal's eventual group assignment.

After injury, animals were randomly allocated to the control group (n=10), which received no additional intervention, or to the treatment group (n=10), which received SprayGel application (Figure 3). During SprayGel application, several locations of punctate bleeding often persisted on each horn and continued even after barrier application. After application of SprayGel on the dorsal surface, saline was used to wet the hydrogel surface; application and wetting were repeated on the ventral surface. The horns were then repositioned in the peritoneal cavity; the musculoperitoneal layers of the incisions were closed by using 4-0 Vicryl suture and the skin was closed by using 4-0 nylon (Ethicon). Animals were monitored for recovery from anesthesia and were observed daily for signs of illness or injury. Historically, this model has produced adhesions in more than 80% of control animals.

Postoperative Evaluation

At 15 days, the rabbits were euthanized by intravenous injection of a sodium pentobarbital–based solution. A blinded observer opened the peritoneal cavity and scored the extent of adhesions by using the following scale: 0, clean, no adhesions; 1, adhesions on up to 25% of the injured area; 2, adhesions on 25%–50% of the injured area; and 3, greater than 50% adhesion involvement. Adhesion severity was scored as follows: 0, clean, no adhesions; 0.5, some resistance (slight force required); and 1, moderate resistance or blunt dissection.

Statistical Analysis

For both the rat and rabbit study data, a χ^2 test was used to compare the rate of adhesion incidence between the treatment and control groups. The Wilcoxon signed-rank test for nonparametric data was used to compare adhesion extent and severity scores between the treatment and control groups (SPSS software, version 9.0; SPSS, Inc., Chicago, IL). $P<.05$ was considered to be statistically significant.

RESULTS

Rat Cecum Abrasion Model

All animals survived the procedure, and none were excluded from the study. The adhesion extent and severity scores in the control and treated rats are shown in Table 1. At harvest, 7 of 8 control animals and 1 of 8 treated animals had adhesions between the cecum and sidewall, which represented a 86% reduction in incidence ($P=.034$). Treated animals had significantly lower extent scores than control animals (0 of 8 treated rats and 6 of 8 control rats had adhesions on $>$ 50% of the cecum; $P=.003$) (Figure 4). Adhesion severity was also significantly reduced in treatment group; 1 of 8 treated rats had dense vascular adhesions compared with 4 of 8 control rats ($P=.015$).

TABLE 1

Adhesion extent and severity scores in the rat cecum abrasion model.[a]

	Adhesion extent		Adhesion severity	
Rat	Control	Treated	Control	Treated
1	2	1	1	2
2	2	0	2	0
3	1	0	1	0
4	2	0	2	0
5	0	0	0	0
6	2	0	2	0
7	2	0	2	0
8	2	0	1	0
P value[b]		.003		.015

[a] See Materials and Methods for explanation of scoring system.
[b] Wilcoxon signed-rank test ($P<.05$ statistically significant).

Dunn. Evaluation of SprayGel Adhesion barrier. Fertil Steril 2001.

Rabbit Uterine Horn Model

All animals survived the procedures, and no animals were excluded. In general, the animals remained in good health for the duration of the study. The animals maintained or gained body weight. Occasional incidence of reduced fecal output, diarrhea, and incision problems (wound exudate, removed sutures) were noted in both treated and control animals; no trends were observed in either group.

Adhesion extent and severity scores for the control and treated rabbits are shown in Table 2. Treated animals had

TABLE 2

Adhesion extent and severity scores in the rabbit uterine horn model.[a]

	Adhesion extent		Adhesion severity	
Rabbit	Control	Treated	Control	Treated
1	3	3	1	1
2	3	1	1	1
3	3	1	1	1
4	3	0	1	0
5	3	3	1	1
6	3	1	1	0.5
7	3	1	1	0.5
8	2	1	1	0.5
9	1	1	1	0.5
10	3	1	1	0.5
P value[b]		.007		.023

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DISCUSSION

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In contrast, the SprayGel adhesion barrier possesses most of the key characteristics required for an ideal adhesion barrier. PEG is a poor food source for bacteria because of its nonbiological origin. Thus, along with the rapid barrier absorption rate, SprayGel does not lend itself readily to the promotion or potentiation of bacterial infection. The synthetic chemistry has been optimized to react rapidly on the tissue to allow for easy deposition and visualization. Since the material transforms from a liquid to a solid hydrogel, it can tenaciously adhere to wet tissues and protect these tissues through the critical repair period. The absorption profile of this material has been tailored to ensure its presence during the critical first 6–7 days of healing. From the time of application to the time of absorption, the hydrogel remains adherent to the surface on which it is applied. The hydrogel barrier itself is more than 90% water at application. Because of this high water content the adhesion barrier presents a highly lubricious and biocompatible interface with the surrounding tissue.

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The uterine horns in the rabbit were smaller (often < 5 mm diameter), thus making application of SprayGel more challenging. The increased difficulty in application to a small structure, along with the punctate bleeding that persisted even after barrier application, are thought to account for the differences in adhesion incidence data between the two models. Rat and rabbit adhesion models have historically been accepted as adequate preclinical predictors of clinical efficacy. However, preclinical models with larger organ sizes, weights and forces, and relevant surgical procedures may be better predictors of efficacy in humans. Thus, further studies in a large animal adhesion formation model that mimics the human surgical environment have been undertaken before human clinical studies are begun.

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on February 21, 2018, I caused true and correct copies of the foregoing document to be served upon the following counsel of record by e-mail:

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EXHIBIT 6

[redacted]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., AND INCEPT LLC, Plaintiffs, v. HYPERBRANCH MEDICAL TECHNOLOGY, INC., Defendant.	C.A. No. 15-819-LPS-CJB

PLAINTIFFS' SECOND SUPPLEMENTAL OBJECTIONS AND ANSWER TO HYPERBRANCH'S INTERROGATORY NO. 1

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, the Local Rules for the U.S. District Court for the District of Delaware, and subject to their rights to supplement these objections later in discovery, Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC (collectively "Plaintiffs," as well as "Integra," "Integra Sales," "Confluent," and "Incept," respectively) hereby provide the following second supplemental objections and responses to Interrogatory No. 1 of Defendant HyperBranch Medical Technology's ("HyperBranch") First Set of Interrogatories (Nos. 1-7) , including each and every definition, instruction, and interrogatory contained therein (collectively "HyperBranch's First Set of Interrogatories"). The fact that Plaintiffs provide an answer to an interrogatory does not constitute an admission or acknowledgement that the interrogatory is proper, that the answers sought are within the bounds of discovery, or that requests for similar information will be treated in a similar fashion. Plaintiffs do not waive any objection by producing such documents, things, or answers, and Plaintiffs reserve the right to continue investigating these matters, to supplement their objections, and to object to future discovery on

the same or related matters. Plaintiffs further reserve the right to object to the admissibility of any answer produced pursuant to these interrogatories, in whole or in part, on any ground including without limitation materiality, relevance, and privilege.

GENERAL OBJECTIONS

Plaintiffs incorporate by reference their General Objections and Objections to Specific Definitions to HyperBranch's Requests for Production. Each of these General Objections is incorporated into the specific objections set forth below, whether or not separately set forth therein.

1. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks to impose upon Plaintiffs any obligation or responsibility broader than, different from, or in addition to those obligations and requirements mandated by the Federal Rules of Civil Procedure, the Federal Rules of Evidence (collectively, the "Federal Rules"), and the Local Rules for the United States District Court for the District of Delaware (the "Local Rules").

2. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks the disclosure of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law. Plaintiffs do not intend to produce such privileged or protected documents or information. To the extent that any document or information which is properly subject to any such privilege or protection is inadvertently produced in connection with an answer to an interrogatory, such inadvertent disclosure is not to be construed as a waiver of such privilege or protection, and such document and information, and all copies thereof, shall be returned to counsel for Plaintiffs, in accordance with Fed. R. Evid. 502(b), Fed. R. Civ. P. 26(b)(5)(B), and any relevant Order entered by the Court. Further,

Plaintiffs will limit their privilege log to pre-lawsuit privileged or protected documents or information, if any exist.

3. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent they contain misstatements of fact and/or inaccurate assumptions. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it is overly broad, unduly burdensome, or oppressive. Plaintiffs further object to each and every definition, instruction, and interrogatory to the extent it calls for information that is irrelevant to any claim or defense in this action.

4. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks information already in the possession, custody, or control of HyperBranch as being overly broad, unduly burdensome, expensive, and inconsistent with the Federal Rules.

5. Plaintiffs object to each and every definition, instruction, and interrogatory as being unduly burdensome to the extent it seeks facts, documents, and/or information that is publicly available, unreasonably cumulative or duplicative, or already known and equally available to HyperBranch.

6. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it is vague, ambiguous, fails to describe the information sought with the required reasonable particularity, or is so unintelligible that Plaintiffs cannot ascertain what information is responsive.

7. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it seeks to impose upon Plaintiffs an obligation to investigate or discover information, materials, or documents from any entity other than Plaintiffs, including, but not limited to, third parties or non-parties.

8. Plaintiffs' agreement to furnish information in response to HyperBranch's Interrogatories shall not be deemed to constitute an admission as to its relevancy, nor is it intended to waive any right to object to its admissibility at trial.

9. Plaintiffs object to each interrogatory that requests "each," "every," or "all" (and to similar overly broad terms) information or documents as overbroad and unduly burdensome. Plaintiffs will undertake a diligent and reasonable investigation to gather information in their possession, custody, or control that is responsive to the non-objectionable portions of each interrogatory.

10. Plaintiffs object to each and every definition, instruction, and interrogatory to the extent it contains subparts, is compound and conjunctive, and is otherwise inconsistent with or exceeds the number of interrogatories permitted by any relevant Order entered by the Court. The Court has set a limit of 25 interrogatories for each side. In answering any or all of these Interrogatories or subparts, Plaintiffs do so without waiver of their right to object to and refuse to answer any future Interrogatories on the grounds that such Interrogatories are in excess of the number permitted by the Federal and Local Rules and the Court's Scheduling Order.

11. In addition to these General Objections, Plaintiffs have specific objections as set forth below. By stating these specific objections, Plaintiffs do not waive any of the General Objections that may also be applicable to specific interrogatories.

OBJECTIONS TO SPECIFIC DEFINITIONS

1. Plaintiffs object to the definition of the terms "Plaintiffs," "You," and "Yours" to the extent those terms are overly broad and purport to require Plaintiffs to provide information and/or documents that are not currently within their possession, custody, or control. Plaintiffs object to the definitions of the terms "Plaintiffs," "You," and "Yours" as seeking the disclosure

of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law, in that the definitions specifically cover "attorneys."

2. Plaintiffs object to the definition of "Accused Products" as overbroad, unduly burdensome, and irrelevant to any issue in this matter as "any and all products, activities, services, processes, systems, apparatuses, or things that Plaintiffs accuse of infringing the Asserted Patents in this Action, including Adherus Autospray Dural Sealant, Adherus Dural Sealant, and Adherus Spinal Sealant" include information, products, and/or documents that are not currently within the possession, custody, or control of Plaintiffs. Indeed, this definition explicitly includes documents and things which are in the exclusive control of Defendant and Third Parties.

3. Plaintiffs object to the definition of the term "each" to the extent that the definition purports to impose a meaning broader than the definition provided in the Federal Rules.

4. Plaintiffs object to the definition of "Prior Art" as overbroad, unduly burdensome, and irrelevant to any issue in this matter as "all things, patents, publications, disclosures, sales, or other acts or occurrences included within the broadest meaning of 35 U.S.C. § 102 (or any subpart thereof) and 35 U.S.C. § 103" and "publications, patents, patent applications, inventions by others, uses, sales or offers for sale, and disclosures" purports to require Plaintiffs to provide information and/or documents that are not currently within their possession, custody, or control.

OBJECTIONS AND ANSWERS TO SPECIFIC INTERROGATORIES

INTERROGATORY NO. 1 [9]. On a claim-by-claim basis for each and every claim of the Asserted Patents, identify each individual who You contend contributed to the conception of the invention set forth in each claim, including all supporting facts and evidence of the contribution to the conception of each claim by the identified individual(s) and the dates of such contribution(s).

OBJECTION AND ANSWER TO INTERROGATORY NO. 1 [9] [served October 27, 2016:

Plaintiffs incorporate their General Objections and Objections to Specific Definitions by reference. Plaintiffs object to this interrogatory to the extent it purports to be a single interrogatory as it contains multiple and distinct subparts. Plaintiffs further object to this interrogatory to the extent it purports to be HyperBranch's first interrogatory. HyperBranch previously served Interrogatory Nos. 1-6 on October 23, 2015, and Interrogatory Nos. 7-8 on December 9, 2015. Thus, this interrogatory is HyperBranch's ninth interrogatory. Plaintiffs further object to this interrogatory as being unreasonably cumulative or duplicative, or already known to HyperBranch. *See* Interrogatory No. 1 served by HyperBranch on October 23, 2015. Plaintiffs further object to this interrogatory to the extent it seeks the disclosure of information protected by the attorney-client privilege, attorney work-product doctrine, common interest privilege, or any other applicable privilege or protection, as provided by any applicable law. Plaintiffs further object to the interrogatory as overbroad and unduly burdensome in that it requests identification of "all supporting facts and evidence of the contribution to the conception of each claim." Plaintiffs further object to this interrogatory as premature and irrelevant to the extent it is a contention interrogatory that seeks to impose a burden on Plaintiffs to provide a rebuttal position on conception of the inventions claimed in the patents-in-suit prior to the provision of any contention of invalidity of the claims that Defendant is required to provide on November 4, 2016. Validity, including validity of conception and proper inventorship is presumed by the issuance of the patent. Defendant bears the burden of establishing through its

invalidity contentions that there is an issue as to validity that would require Plaintiffs to prove an earlier date of invention or confirm the contribution of a listed inventor to the claims of the patents-in-suit. To date, Defendants validity contentions have not met that burden. Plaintiffs also object to this interrogatory to the extent it calls for legal argument and/or expert testimony, which Plaintiffs may provide, in due course and in accordance with the Court's Scheduling Order.

Subject to and without waiving its objections, Plaintiffs incorporate by reference their response to Interrogatory No. 1 served on November 13, 2015 and all supplements thereto and the Rebuttal Expert Report of Dr. Jimmy Mays and further respond that based on present information Chandrashekhar P. Pathak, Amarpreet S. Sawhney, and Peter G. Edelman contributed to the conception of one or more claims of the '034 Patent, the '406 Patent, the '5,705 Patent, the '566 Patent and the '418 Patent. Plaintiffs further respond that based on present information Amarpreet S. Sawhney, Steven Bennett, and Peter G. Edelman contributed to the conception of one or more claims of the '3,705 Patent. Defendants' present invalidity contentions do not place in dispute the conception or the named inventor's individual contributions to conception of any of the claims. Accordingly, Plaintiffs presently intend to rely on the effective filing date for each of patents-in-suit (including those patents and patent applications to which priority is claimed), including any evidence presented during prosecution of the patents-in-suit (including those patents and patent applications to which priority is claimed), the recitation of the named inventors on the face of each of the patents-in-suit, and the prior sworn deposition testimony (including exhibits used in those depositions) in this matter of the named inventors to identify the dates and individuals contributing to the conception of each of the claims of the patents-in-suit and the prior sworn testimony and multiple expert reports,

rebuttal expert reports, and/or declarations of Dr. Jimmy Mays that have previously been provided in this matter. Plaintiffs further respond that they have produced non-privileged documents pursuant to Federal Rule of Civil Procedure 33(d) (including the patents-in-suit, the patents and applications from which the patents-in-suit claim priority, the prosecution histories of these patents and patent applications, and the laboratory notebooks and the reports summarizing the laboratory work and notebooks of the inventors and individuals working under their direction (*See, e.g.,* Experimental Reports or Technical Documents having an ER[###] or TD-[###] identification)) from which HyperBranch may derive or ascertain information responsive to this interrogatory. Investigation of the facts is ongoing and Plaintiffs reserve the right to supplement this response to identify additional information and/or documents as more facts arise in discovery or as Defendant's invalidity contentions are fully and completely provided, in accordance with the Rules.

SUPPLEMENTAL OBJECTION AND ANSWER TO INTERROGATORY NO. 1[9] [served December 9, 2016]:

Subject to and without waiving any of its objections, based on information currently available to Plaintiffs and further to the Court's Order during the telephone conference on December 1, 2016, Plaintiffs supplement their previous response by stating that to the extent that Plaintiffs understand this interrogatory, Plaintiffs identify the following individuals who Plaintiffs currently contend to have contributed to the conception of the inventions set forth in the Asserted Claims and Plaintiffs contentions as to the date of conception of the inventions set forth in the Asserted Claims (to the extent that the "Earlier Conception Date" column is blank for any respective row, in the following tables, Plaintiffs are currently relying on the "Earlier Effective Filing Date" as also the "Earlier Conception Date"):

U.S. Patent 7,009,034

Claim	Earlier Effective Filing Dates	Earlier Conception Date*	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
3	December 4, 1998 and December 3, 1999		Pathak
4	December 4, 1998 and December 3, 1999		Pathak
5	December 4, 1998 and December 3, 1999		Pathak
6	November 9, 2001	February 2001	Pathak, Sawhney, Edelman
9	December 4, 1998 and December 3, 1999		Pathak
10	November 9, 2001		Pathak, Sawhney, Edelman
11	December 4, 1998 and December 3, 1999		Pathak
12	December 4, 1998 and December 3, 1999		Pathak
13	December 4, 1998 and December 3, 1999		Pathak
14	December 3, 1999		Pathak
15	December 4, 1998 and December 3, 1999		Pathak
16	December 4, 1998 and December 3, 1999		Pathak
17	December 3, 1999		Pathak
18	December 4, 1998 and December 3, 1999		Pathak
19	December 4, 1998 and December 3, 1999		Pathak
20	December 4, 1998 and December 3, 1999		Pathak
21	December 4, 1998 and December 3, 1999		Pathak

U.S. Patent No. 7,332,566

Claim	Earlier Effective Filing Dates	Earlier Conception Date	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
3	November 9, 2001	February 2001	Pathak, Sawhney, Edelman

4	December 4, 1998 and December 3, 1999		Pathak
6	December 4, 1998 and December 3, 1999		Pathak
7	November 9, 2001		Pathak, Sawhney, Edelman
8	December 4, 1998 and December 3, 1999		Pathak
9	November 9, 2001		Pathak, Sawhney, Edelman
10	December 3, 1999		Pathak
11	December 4, 1998 and December 3, 1999		Pathak
12	December 4, 1998 and December 3, 1999		Pathak
14	December 4, 1998 and December 3, 1999		Pathak
15	November 9, 2001		Pathak, Sawhney, Edelman
16	December 4, 1998 and December 3, 1999		Pathak
18	December 4, 1998 and December 3, 1999		Pathak
19	November 9, 2001		Pathak, Sawhney, Edelman
20	December 4, 1998 and December 3, 1999		Pathak
21	December 4, 1998 and December 3, 1999		Pathak
22	December 4, 1998 and December 3, 1999		Pathak
23	November 9, 2001		Pathak, Sawhney, Edelman
24	December 4, 1998 and December 3, 1999		Pathak
25	December 4, 1998 and December 3, 1999		Pathak
27	November 9, 2001	February 2001	Pathak, Sawhney, Edelman
28	December 4, 1998 and December 3, 1999		Pathak
30	December 4, 1998 and December 3, 1999		Pathak
31	November 9, 2001		Pathak, Sawhney, Edelman
32	December 3, 1999		Pathak

33	December 4, 1998 and December 3, 1999		Pathak
34	November 9, 2001		Pathak, Sawhney, Edelman
35	December 4, 1998 and December 3, 1999		Pathak
36	December 4, 1998 and December 3, 1999		Pathak
37	December 4, 1998 and December 3, 1999		Pathak
38	November 9, 2001		Pathak, Sawhney, Edelman

U.S. Patent No. 7,592,418

Claim	Earlier Effective Filing Dates	Conception Date	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
3	December 4, 1998 and December 3, 1999		Pathak
4	November 9, 2001	February 2001	Pathak, Sawhney, Edelman
5	December 4, 1998 and December 3, 1999		Pathak
6	December 4, 1998 and December 3, 1999		Pathak
7	November 9, 2001		Pathak, Sawhney, Edelman
8	December 3, 1999		Pathak
9	December 4, 1998 and December 3, 1999		Pathak
10	November 9, 2001		Pathak, Sawhney, Edelman
11	December 4, 1998 and December 3, 1999		Pathak
13	December 4, 1998 and December 3, 1999		Pathak
14	December 4, 1998 and December 3, 1999		Pathak
15	December 4, 1998 and December 3, 1999		Pathak
16	December 4, 1998 and December 3, 1999		Pathak
22	December 4, 1998 and December 3, 1999		Pathak

23	December 4, 1998 and December 3, 1999		Pathak
24	December 4, 1998 and December 3, 1999		Pathak
25	December 4, 1998 and December 3, 1999		Pathak
26	November 9, 2001		Pathak, Sawhney, Edelman
27	December 4, 1998 and December 3, 1999		Pathak
28	December 4, 1998 and December 3, 1999		Pathak
29	December 4, 1998 and December 3, 1999		Pathak
30	November 9, 2001		Pathak, Sawhney, Edelman

U.S. Patent No. 6,566,406

Claim	Earlier Effective Filing Dates	Conception Dates	Inventors
1	December 4, 1998		Pathak
2	December 4, 1998		Pathak
6	December 4, 1998		Pathak
7	December 4, 1998		Pathak
8	December 4, 1998		Pathak
10	December 4, 1998		Pathak
12	December 4, 1998		Pathak
14	December 3, 1999		Pathak, Sawhney, Edelman
15	December 3, 1999		Pathak, Sawhney, Edelman
16	December 4, 1998		Pathak
19	December 4, 1998		Pathak
21	December 4, 1998		Pathak
23	December 3, 1999		Pathak, Sawhney, Edelman
24	December 3, 1999		Pathak, Sawhney, Edelman
25	December 3, 1999		Pathak, Sawhney, Edelman

U.S. Patent No. 8,003,705

Claim	Earlier Effective Filing Dates	Conception Dates	Inventors
1	May 28, 2008	December 2000	Sawhney, Bennett, Edelman
4	November 9, 2001		Sawhney, Edelman
5	November 9, 2001		Sawhney, Edelman
6	November 9, 2001		Sawhney, Edelman
11	November 9, 2001		Sawhney, Edelman
12	November 9, 2001		Sawhney, Edelman
13	November 9, 2001		Sawhney, Edelman
16	May 28, 2008	December 2000	Sawhney, Bennett, Edelman
19	May 28, 2008	December 2000	Sawhney, Bennett, Edelman

U.S. Patent No. 8,535,705

Claim	Earlier Effective Filing Dates	Conception Dates	Inventors
1	December 4, 1998 and December 3, 1999		Pathak
5	December 4, 1998 and December 3, 1999		Pathak
6	December 4, 1998 and December 3, 1999		Pathak
7	December 4, 1998 and December 3, 1999		Pathak
9	December 3, 1999		Pathak, Sawhney, Edelman
12	December 4, 1998 and December 3, 1999		Pathak
15	December 4, 1998 and December 3, 1999		Pathak
17	December 4, 1998 and December 3, 1999		Pathak

SECOND SUPPLEMENTAL OBJECTION AND ANSWER TO INTERROGATORY NO. 1[9] [served February 23, 2018]:

Subject to and without waiving any of its objections and based on HyperBranch's improper efforts[1] to include a new invalidity theory with respect to claim 10 of the '034 patent in

[1] On February 21, 2018 Plaintiffs moved to strike these portions of Dr. Lowman's Supplemental Report as violating this Court's October 24, 2017 Order (*see* D.I. 510, 511). In addition,

Dr. Lowman's February 14, 2018 Supplemental Report that is not previously identified as one of the 24 grounds elected by Defendant in their final invalidity contentions (even though the underlying document cited by Defendant is identified on the face of the '034 Patent), Plaintiffs hereby supplement their previous response by stating that to the extent that Plaintiffs understand this interrogatory, Plaintiffs incorporate by reference Dr. Mays' February 21, 2018 Surreply Supplemental Expert Report and all facts, exhibits, and declarations set forth or referenced therein that show that claim 10 of the '034 Patent is also entitled to a priority date (and a conception date) of at least February 2001. Plaintiffs reserve the right to amend or supplement this response as this case proceeds.

AS TO OBJECTIONS ONLY:

DATED: February 23, 2018

/s/ Karen L. Pascale

An Attorney for Plaintiffs, Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC

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(Continued . . . .)

Plaintiffs served Dr. Mays's February 21, 2018 Surreply Supplemental Expert Report (including all exhibits thereto) showing that even if Defendant's new invalidity theory were to be allowed by the Court in contravention to its previous order, the supplementation would be futile because the basis for Defendant's new invalidity theory is not prior art to claim 10 of the '034 Patent.

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CERTIFICATE OF SERVICE

I, Karen L. Pascale, Esquire, hereby certify that on February 23, 2018, I caused true and correct copies of the foregoing document to be served upon the following counsel of record by e-mail:

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